

# MONTANA ADMINISTRATIVE REGISTER

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# MONTANA ADMINISTRATIVE REGISTER

## ISSUE NO. 1

The Montana Administrative Register (MAR or Register), a twice-monthly publication, has three sections. The Proposal Notice Section contains state agencies' proposed new, amended, or repealed rules; the rationale for the change; date and address of public hearing; and where written comments may be submitted. The Rule Adoption Section contains final rule notices which show any changes made since the proposal stage. All rule actions are effective the day after publication of the adoption notice unless otherwise specified in the final notice. The Interpretation Section contains the Attorney General's opinions and state declaratory rulings. Special notices and tables are found at the end of each Register.

Inquiries regarding the rulemaking process, including material found in the Montana Administrative Register and the Administrative Rules of Montana, may be made by calling the Secretary of State's Office, Administrative Rules Services, at (406) 438-6122.

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BEFORE THE DEPARTMENT OF COMMERCE  
OF THE STATE OF MONTANA

In the matter of the amendment of ) NOTICE OF PUBLIC HEARING ON  
ARM 8.111.602 definitions and ) PROPOSED AMENDMENT  
8.111.603 housing credit allocation )  
procedure )

TO: All Concerned Persons

1. On February 3, 2022, at 10:00 a.m., the Department of Commerce will hold a public hearing via Zoom to consider the proposed amendment of the above-stated rules. Interested parties may access the remote conferencing platform in the following ways:

a. Video:

<https://mt.gov.zoom.us/j/88581620373?pwd=TWNRVGVYbEJIV1F0RExGSnRsK2JGQT09>

Meeting ID: 885 8162 0373

Password: 222280

b. Phone: Dial in by Telephone: 406-444-9999

Meeting ID: 885 8162 0373

Password: 222280

2. The Department of Commerce will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact the Department of Commerce no later than 5:00 p.m., February 2, 2022, to advise us of the nature of the accommodation that you need. Please contact Bonnie Martello, Department of Commerce, 301 South Park Avenue, P.O. Box 200501, Helena, Montana 59620-0523; telephone (406) 841-2596; TDD 841-2702; fax (406) 841-2771; or e-mail [docadministrativerules@mt.gov](mailto:docadministrativerules@mt.gov).

3. The rules proposed to be amended provide as follows, new matter underlined, deleted matter interlined:

8.111.602 DEFINITIONS (1) and (2) remain the same.

(3) "QAP" means the board's "Housing Credit Program ~~2022~~ 2023 Qualified Allocation Plan," which sets forth the application process and selection criteria used by the board for evaluation and selection of projects to receive awards for allocation of housing credits for calendar year ~~2022~~ 2023. The board adopts and incorporates by reference the Housing Credit Program ~~2022~~ 2023 Qualified Allocation Plan, copies of which may be obtained by contacting the Board of Housing by mail at P.O. Box 200528, Helena, MT 59620-0528, by telephone at (406) 841-2845 or (406) 841-2838, or at the board's web site [www.housing.mt.gov](http://www.housing.mt.gov).

(4) "QCP" or "Qualified contract process" means the board's "Qualified Contract Policy dated November 15, 2021," which sets forth the requirements and process that governs qualified contract requests by owners of housing credit projects. The board adopts and incorporates by reference the Qualified Contract Policy dated November 15, 2021, copies of which may be obtained by contacting the Board of Housing by mail at P.O. Box 200528, Helena, MT 59620-0528, by telephone at (406) 841-2845 or (406) 841-2838, or at the board's web site [www.housing.mt.gov](http://www.housing.mt.gov).

(4) (5) "Tax credit" or "housing credit" means the federal low income housing tax credit for owners of qualifying rental housing which meets certain low income occupancy and rent limitation requirements pursuant to 26 U.S.C. 42.

AUTH: 90-6-106, MCA

IMP: 90-6-104, MCA

REASON: The proposed amendments to ARM 8.111.602 are necessary to adopt and incorporate by reference the board's Housing Credit Program 2023 Qualified Allocation Plan (QAP) and the board's Qualified Contract Policy dated November 15, 2021.

Federal low income housing tax credits are allocated by the federal government to the states, according to their population, for allocation to particular buildings. Each state's share of federal low income housing tax credits is allocated to particular buildings under programs administered by the respective states' housing credit agencies. The Montana Board of Housing (MBOH) is Montana's housing credit agency for purposes of administering the tax credit program and allocating tax credits in the state of Montana. In Montana, the program is known as the Montana Housing Credit Program. Federal law requires that tax credits allocated to the state by the federal government must be allocated by the state pursuant to a "qualified allocation plan" or "QAP."

Prior to publication of this notice, the board conducted several public meetings to consider suggestions and comments regarding the provisions of the 2023 QAP. Thereafter, at its September 13, 2021 meeting, the board considered and approved public notice and distribution of the proposed 2023 QAP. After public notice of the proposed 2023 QAP and of the opportunity for public comment was published and distributed, a public hearing on the proposed 2023 QAP was held on October 27, 2021, and written comments were also received. At its November 15, 2021 meeting, after considering all written and oral comments on the proposed 2023 QAP, staff recommendations, additional public comment and various proposed revisions in response to comments, the board approved the 2023 QAP for submission to and approval by the Montana Governor, as required by the federal tax credit statute, 26 U.S.C. § 42. Adoption of the proposed rule is contingent upon the Governor's approval of the 2023 QAP.

A copy of the 2023 QAP is available on the internet at <https://housing.mt.gov> or by requesting a copy from: Nicole McKeith, Board of Housing, Department of

Commerce, 301 South Park Avenue, P.O. Box 200528, Helena, Montana, 59620-0528; telephone (406) 841-2048; fax (406) 841-2841; or e-mail nicole.McKeith@mt.gov.

As a condition of receiving housing credits, the project owner must execute and record restrictive covenants running with the project land which are subject to certain affordability and other requirements for the duration of a specified extended use period. At the end of the initial 15-year compliance period, federal law allows the owner to request that the board find a person, who will continue to operate the project under the restrictive covenants, to acquire the owner's interest in the project for the qualified contract amount determined according to federal law.

If the board provides a qualified offer from a proposed buyer within a one-year period, the project will remain subject to the restrictive covenants for the entire extended use period, regardless of whether the owner accepts the qualified contract. If the board does not find a qualified offer within the one-year period, the extended use period and the restrictive covenants will terminate, subject to certain tenant protections that will continue for a three-year period.

Federal laws and regulations specify certain requirements of this process, but largely leave the establishment and enforcement of processes and requirements to each state housing credit agency. Adoption of the Qualified Contract Policy is necessary to establish the board's requirements and processes for submission and processing of qualified contract requests.

The qualified contract process potentially allows the owner to remove affordability restrictions from the project before the end of the extended use period, allowing the owner to charge higher market rents and change other project characteristics designed to benefit low-income tenants. This potentially reduces the stock of affordable housing units and is contrary to MBOH's mission to preserve and increase the availability of affordable housing.

Adoption and enforcement of a strict policy and process are necessary to protect the state's stock of affordable housing to the greatest extent possible by ensuring that affordable housing credit projects are removed from affordability only after full and strict compliance with procedures designed to ensure that an offer is received from a qualified buyer whenever possible.

The policy specifies the eligibility requirements for submission of a request, the required manner and content of a request submission, specifies the process followed for consideration and implementation of a request, and specifies the fees and expenses that must be paid by the owner. The requirements and processes in the policy are necessary to ensure that affordable housing credit projects are removed from affordability only after full and strict compliance with procedures designed to assure that an offer is received from a qualified buyer whenever possible.

8.111.603 HOUSING CREDIT ALLOCATION PROCEDURE (1) ~~Letters of intent and applications for housing credits shall be prepared and submitted in conformance with the criteria and requirements contained in the QAP. The board's processes, criteria, and related procedures and requirements applicable to application, evaluation, and selection of projects for allocation of housing credits and for housing credit compliance are set forth in the QAP.~~

~~(2) Letters of intent and applications shall be submitted to the board on the dates specified in or otherwise designated according to the QAP. The board may extend or change any of the submission, presentation, or meeting dates or deadlines specified in the QAP if circumstances warrant, and in such event, the board will provide notice of such extension or change by posting on its web site.~~

~~(3) All projects wishing to apply for housing credits must submit a letter of intent in accordance with the requirements of the QAP.~~

~~(a) At the board's meeting in the month specified in or established in accordance with the QAP, board staff will present letters of intent to the board and the board will provide an opportunity for applicants to make a presentation regarding their projects and letters of intent and for public comment on proposed projects and letters of intent, all according to the provisions of the QAP. The board may ask questions of applicants and discuss proposed projects for purposes of assisting the board in determining which projects it will invite to submit applications and assisting applicants in presenting better applications, but such questions, answers, and discussion shall not be binding upon the board in any later award determination or other board process.~~

~~(b) After considering the letters of intent, presentations, questions and answers and discussion, the board will select those projects that it will invite to submit applications, in accordance with the provisions of the QAP. Each project so selected by the board will be deemed invited to submit an application. An application may be submitted only for a project invited by the board to submit an application and all other applications will be returned without consideration.~~

~~(4) Following submission of applications, board staff will review and evaluate each invited application for conformance with the threshold and other requirements of the QAP. Applications meeting all minimum threshold requirements and not excluded from further consideration under the QAP will be reviewed and evaluated according to all applicable QAP criteria and requirements, including but not limited to determining the amount of housing credits needed for feasibility and long term viability, and evaluation and scoring according to the development evaluation criteria of the QAP. The points awarded to each project pursuant to the development evaluation criteria and scoring provisions of the QAP are for the purposes specified in (9), and not for purposes of ranking projects for allocation of housing credits. Following application review, evaluation and scoring, board staff may provide recommendations to the board for allocation of housing credits to qualifying projects.~~

~~(5) At the board's award determination meeting, board staff will provide application information to the board and the board will provide an opportunity for public comment on proposed projects and applications, all according to the provisions of the QAP. The board may ask questions of applicants and discuss proposed projects but there will be no applicant presentations.~~



(6) (2) Copies of applications and other information submitted to the board in connection with applications are available to other applicants for housing credit projects and members of the public to the extent provided and according to the procedures specified in the board's information request and release policy, available on the Department of Commerce web site at <https://commerce.mt.gov/Contact/Legal> <https://commerce.mt.gov/>.

(7) (3) At one or more regularly scheduled board meetings each year, as specified in or otherwise designated according to the QAP, the board will hear public comment and consider award of housing credit allocations in accordance with the QAP. The award of housing credit allocations is not a contested case and the award meeting is not a contested case hearing under Title 2, chapter 4, part 6, MCA.

~~(8) At the award determination meeting provided under (7), applicants should be available to the board to answer questions regarding their respective applications and shall be provided a brief opportunity to make comments and respond to any information presented regarding their applications.~~

~~(9) The board will select those projects to receive an award of housing credits that it determines best meet the most pressing affordable housing needs of low income people within the state of Montana, taking into consideration the selection criteria as defined in the QAP. The awarding of points to projects pursuant to the development evaluation criteria of the QAP is for purposes of determining that the projects meet at least the minimum criteria required for further consideration under the QAP and to assist the board in evaluating and comparing projects. Development evaluation criteria scoring is only one of several considerations taken into account by the board and does not control the selection of projects that will receive an award of housing credits. In addition to any other selection criteria specified in the QAP, the board may consider the following factors in selecting projects for an award of housing credits to qualifying projects:~~

- ~~(a) the geographical distribution of housing credit projects;~~
- ~~(b) the rural or urban location of the projects;~~
- ~~(c) the overall income levels targeted by the projects (including deeper targeting of income levels);~~
- ~~(d) the need for affordable housing in the community, including but not limited to current vacancy rates;~~
- ~~(e) rehabilitation of existing low income housing stock;~~
- ~~(f) sustainable energy savings initiatives;~~
- ~~(g) financial and operational ability of the applicant to fund, complete, and maintain the project through the extended use period;~~
- ~~(h) past performance of an applicant in initiating and completing tax credit projects;~~
- ~~(i) cost of construction, land, and utilities, including but not limited to costs/credits per square foot/unit;~~
- ~~(j) the project is being developed in or near a historic downtown neighborhood;~~
- ~~(k) the frequency of awards in the respective areas where projects are located;~~
- ~~(l) preserving project rental assistance or having or planning to add Section 811 units to an existing project (Section 811 units are units subsidized by the United~~

~~States Department of Housing and Urban Development with available supportive services for very low income and extremely low income adults with disabilities); and/or~~  
~~(m) augmentation and/or sources of funds.~~

AUTH: 90-6-106, MCA

IMP: 90-6-104, MCA

REASON: The proposed amendments to ARM 8.111.603 are necessary to delete material that unnecessarily duplicates provisions of the QAP. The QAP specifies the procedures and requirements set forth in the provisions proposed for deletion. Since the QAP is adopted and incorporated by reference in ARM 8.111.602(3), such material is already in rule and the deleted rule materials are duplicative and unnecessary.

4. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to the Department of Commerce, 301 South Park Avenue, P.O. Box 200523, Helena, Montana 59620-0523; telephone (406) 841-2770; TDD 841-2702; fax (406) 841-2771; or e-mail [docadministrativerules@mt.gov](mailto:docadministrativerules@mt.gov), and must be received no later than 5:00 p.m., February 11, 2022.

5. The Office of Legal Affairs, Department of Commerce, has been designated to preside over and conduct this hearing.

6. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to the contact person in 4 above or may be made by completing a request form at any rules hearing held by the department

7. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

8. With regard to the requirements of 2-4-111, MCA, the department has determined that the amendment of the above-referenced rules will not significantly and directly impact small businesses.

MONTANA BOARD OF HOUSING  
Patrick E. Melby, Chair

/s/ Amy Barnes  
Amy Barnes  
Rule Reviewer

/a/ Adam Schafer  
Adam Schafer  
Deputy Director  
Department of Commerce

Certified to the Secretary of State January 4, 2022.

BEFORE THE FISH AND WILDLIFE COMMISSION  
OF THE STATE OF MONTANA

In the matter of the amendment of ) NOTICE OF PUBLIC HEARING ON  
ARM 12.9.1403 pertaining to grizzly ) PROPOSED AMENDMENT  
bear demographic objective for the )  
Northern Continental Divide )  
Ecosystem )

TO: All Concerned Persons

1. On February 8, 2022, at 1:30 p.m., the Fish and Wildlife Commission (commission) will hold a telephonic public hearing via the ZOOM meeting platform to consider the proposed amendment of the above-stated rule. There will be no in-person hearing. Interested parties may access the remote conferencing in the following way:

(a) Dial by telephone: 1 206 337 9723  
Meeting ID: 899 9202 1036  
Password: 948944

2. The commission will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact the Department of Fish, Wildlife and Parks (FWP), no later than 5:00 p.m. on January 28, 2022, to advise us of the nature of the accommodation that you need. Please contact Jessica Snyder, Department of Fish, Wildlife and Parks, P.O. Box 200701, Helena, Montana, 59620-0701; telephone (406) 444-9785; or e-mail [jesssnyder@mt.gov](mailto:jesssnyder@mt.gov).

3. The rule as proposed to be amended provides as follows, new matter underlined, deleted matter interlined:

12.9.1403 GRIZZLY BEAR DEMOGRAPHIC OBJECTIVES FOR THE NORTHERN CONTINENTAL DIVIDE ECOSYSTEM (1) Upon delisting from the Endangered Species Act, management of the grizzly bear and its habitat in the Northern Continental Divide Ecosystem (NCDE) will be guided by the Conservation Strategy for Grizzly Bears in the Northern Continental Divide Ecosystem (NCDE Conservation Strategy). The department and federal land management agencies will endorse and commit themselves to the NCDE Conservation Strategy by entering into a memorandum of understanding detailing their agreement to implement it. The department will be a signatory to the implementation memorandum.

(2) ~~When and so long as the NCDE Conservation Strategy is in effect, the~~ department and the commission shall, within their lawful authority to do so, maintain the recovered status of the grizzly bear in the NCDE by implementing interagency cooperation, population and habitat management and monitoring, and other

provisions of the NCDE Conservation Strategy in accordance with the responsibilities described therein.

(3) ~~Specific to population management in the NCDE, aAs~~ described in the NCDE Conservation Strategy, the commission specifically adopts the following demographic objectives. The department shall:

(a) maintain a well-distributed grizzly bear population within the demographic monitoring area as described in the NCDE Conservation Strategy and maintain the documented presence of females with offspring in at least 21 of 23 bear management units of the primary conservation area and in at least six of seven occupancy units of Zone 1 at least every six years. Adherence to this objective will be evaluated by monitoring the presence of females with offspring (cubs, yearlings, or 2-year-olds) within defined geographic units of the NCDE;

(b) manage mortalities from all sources, including hunting and the loss of grizzly bears by translocation out of the NCDE, to support an estimated probability of at least 90% that the grizzly bear population within the demographic monitoring area remains above 800 bears, considering the uncertainty associated with all of the demographic parameter and further manage mortality against a 6-year running average within the following threshold objectives:

(i) ~~using a 6-year running average~~, maintain estimated annual survival rate of independent females within the demographic monitoring area of at least 90% and a rate at or above the minimum level consistent with a projected probability of at least 90% that the population within the demographic monitoring area will remain above 800 bears based on population modeling;

(ii) ~~using a 6-year running average~~, limit annual estimated number of total reported and unreported mortalities of independent females within the demographic monitoring area to a number that is no more than 10% of the number of independent females estimated within the demographic monitoring area based on population modeling and a number that is at or below the maximum level consistent with a projected probability of at least 90% that the population within the demographic monitoring area will remain above 800 bears based on population modeling; and

(iii) ~~using a 6-year running average~~, limit annual estimated number of total reported and unreported mortalities of independent males within the demographic monitoring area to a number that is no more than 15% of the number of independent males estimated within the demographic monitoring area based on population modeling.

(c) monitor demographic and genetic connectivity among populations by the following means:

(i) estimating spatial distribution of the NCDE grizzly bear population biennially; and

(ii) identifying the population of origin for individuals sampled inside and outside of the demographic monitoring area to detect movements of individuals to and from other populations or recovery areas.

(4) Hunting would cease if the probability that the grizzly bear population remains above 800 within the demographic monitoring area falls below 90% and would not resume until the probability is 90% or greater that the population of bears remains above 800.

(5) Hunting will not be allowed in a year if mortality thresholds as described in (3)(b)(ii) and (iii) were exceeded in the previous year.

AUTH: 87-1-301, MCA

IMP: 87-1-201, 87-1-301, MCA

REASON: In 2018, the commission passed a regulatory mechanism for grizzly bear management in the event that the threatened grizzly bear under the federal Endangered Species Act was delisted and management authority transferred to the State of Montana. ARM 12.9.1403 is intended to provide for management objectives that would ensure the continued recovered status of grizzly bear upon delisting. The rule commits to the standards outlined in the NCDE Conservation Strategy for presence of females in the NCDE, managing mortalities, and committing to monitoring connectivity.

To maintain recovered status, commitments in ARM 12.9.1403 would remain in place after delisting. Delisting would allow the commission to authorize hunting in a manner consistent with management objectives described in ARM 12.9.1403. To ensure the grizzly bear would remain in recovered status with state management, the regulatory mechanisms are most effective if they indicate how the state will manage populations, including when hunting is no longer viewed to be appropriate. The proposed amendments maintain the substance of the current rule language while confirming that hunting has been and will continue to be a source of mortality measured and considered among other mortalities in ARM 12.9.1403 as will grizzly bears translocated outside the NCDE.

4. Concerned persons may submit their data, views, or arguments orally at the telephonic hearing. Written data, views, or arguments may also be submitted to: Grizzly Bear ARM, Department of Fish, Wildlife and Parks, P.O. Box 200701, Helena, Montana, 59620-0701; or e-mail GrizzlyBearARM@mt.gov, and must be received no later than February 18, 2022.

5. Jessica Snyder or another hearing officer appointed by the department has been designated to preside over and conduct the hearing.

6. The department maintains a list of interested persons who wish to receive notice of rulemaking actions proposed by the department or commission. Persons who wish to have their name added to the list shall make a written request that includes the name and mailing address of the person to receive the notice and specifies the subject or subjects about which the person wishes to receive notice. Such written request may be mailed or delivered to: Department of Fish, Wildlife and Parks, Legal Unit, P.O. Box 200701, 1420 East Sixth Avenue, Helena, MT 59620-0701, or may be emailed to jesssnyder@mt.gov.

7. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

8. With regard to the requirements of 2-4-111, MCA, the commission has determined that the amendment of the above-referenced rule will not significantly and directly impact small businesses.

/s/ Rebecca Dockter  
Rebecca Dockter  
Rule Reviewer

/s/ Lesley Robinson  
Lesley Robinson  
Chair  
Fish and Wildlife Commission

Certified to the Secretary of State January 4, 2022.

BEFORE THE FISH AND WILDLIFE COMMISSION  
OF THE STATE OF MONTANA

In the matter of the adoption of NEW ) NOTICE OF PUBLIC HEARING ON  
RULE I pertaining to recreational use ) PROPOSED ADOPTION  
on the Boulder River )

TO: All Concerned Persons

1. On February 15, 2022, at 1:30 p.m., the Fish and Wildlife Commission (commission) will hold a telephonic public hearing via the ZOOM meeting platform to consider the proposed adoption of the above-stated rule. There will be no in-person hearing. Interested parties may access the remote conferencing in the following way:

(a) Dial by telephone: 1 206 337 9723  
Meeting ID: 873 6209 1322  
Password: 549389

2. The commission will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact the Department of Fish, Wildlife and Parks (FWP), no later than 5:00 p.m. on January 28, 2022, to advise us of the nature of the accommodation that you need. Please contact Jessica Snyder, Department of Fish, Wildlife and Parks, P.O. Box 200701, Helena, Montana, 59620-0701; telephone (406) 444-9785; or e-mail [jesssnyder@mt.gov](mailto:jesssnyder@mt.gov).

3. The rule as proposed to be adopted provides as follows:

NEW RULE I BOULDER RIVER (1) The Boulder River and its tributaries are closed to all motorized watercraft, as defined in 23-2-502, MCA, except:

(a) motorized watercraft 10 horsepower or less are permitted from the Natural Bridge Falls to the Yellowstone River from April 1 to September 30.

AUTH: 87-1-303, MCA  
IMP: 87-1-303, MCA

REASON: In September of 2020, the Fish and Wildlife Commission received a petition requesting the Boulder River and its tributaries be closed to motorized use. The commission considered the petition during their meeting on October 22, 2020. The commission denied the petition and directed the Department of Fish, Wildlife and Parks to create a citizens advisory committee to evaluate boating use on the Boulder River. The department recruited and selected a five-person citizens advisory committee representing diverse interests and backgrounds. The committee evaluated several alternatives including no action, a full motorized ban, allocated days for motorized use, horsepower restrictions, seasonal restrictions, and



motorized restrictions on specific reaches of the river. The committee's final recommendation proposed closing the Boulder River and its tributaries to motorized vessels, except motorized vessels powered by machinery of 10 horsepower or less are permitted from April 1 through September 30 from the confluence with the Yellowstone River to the Natural Bridge. The commission is proposing the committee's recommendation.

4. Concerned persons may submit their data, views, or arguments orally at the telephonic hearing. Written data, views, or arguments may also be submitted to Phil Kilbreath, Department of Fish, Wildlife and Parks, P.O. Box 200701, Helena, Montana, 59620-0701; or e-mail [pkilbreath@mt.gov](mailto:pkilbreath@mt.gov), and must be received no later than February 18, 2022.

5. Jessica Snyder or another hearing officer appointed by the department has been designated to preside over and conduct the hearing.

6. The department maintains a list of interested persons who wish to receive notice of rulemaking actions proposed by the department or commission. Persons who wish to have their name added to the list shall make a written request that includes the name and mailing address of the person to receive the notice and specifies the subject or subjects about which the person wishes to receive notice. Such written request may be mailed or delivered to: Department of Fish, Wildlife and Parks, Legal Unit, P.O. Box 200701, 1420 East Sixth Avenue, Helena, MT 59620-0701, or may be emailed to [jesssnyder@mt.gov](mailto:jesssnyder@mt.gov).

7. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

8. With regard to the requirements of 2-4-111, MCA, the commission has determined that the adoption of the above-referenced rule will not significantly and directly impact small businesses.

/s/ Zach Zipfel  
Zach Zipfel  
Rule Reviewer

/s/ Lesley Robinson  
Lesley Robinson  
Chair  
Fish and Wildlife Commission

Certified to the Secretary of State January 4, 2022.

BEFORE THE DEPARTMENT OF ENVIRONMENTAL QUALITY  
OF THE STATE OF MONTANA

In the matter of the adoption of New	)	NOTICE OF PUBLIC HEARING ON
Rules I through III, the amendment of	)	PROPOSED ADOPTION,
ARM 17.53.105, 17.53.107,	)	AMENDMENT, AND REPEAL
17.53.111, 17.53.112, 17.53.113,	)	
17.53.301, 17.53.502, 17.53.602,	)	
17.53.603, 17.53.701, 17.53.802,	)	(HAZARDOUS WASTE)
17.53.902, 17.53.1002, and	)	
17.53.1302, and the repeal of ARM	)	
17.53.401, 17.53.402, and 17.53.403	)	
pertaining to incorporation by	)	
reference and hazardous waste fees	)	

TO: All Concerned Persons

1. On February 9, 2022, at 2:00 p.m., the Department of Environmental Quality (department) will hold a public hearing in Room 111 of the Metcalf Building, 1520 East Sixth Avenue, Helena, Montana, to consider the proposed adoption, amendment, and repeal of the above-stated rules.

The department is committed to preventing the spread of COVID-19 and promoting the health and wellness of others. Members of the public may participate either in person or virtually. For in-person meetings, while face masks are not required, meeting attendees are welcome to wear masks. If you are not feeling well, please do not attend the in-person meeting. Registration with Zoom may be made at the following link: Join Zoom Meeting

<https://mt-gov.zoom.us/j/86001610494?pwd=U2tlSFIUb1RsZk9JeFpoV2VCcmR3dz09>

Meeting ID: 860 0161 0494  
Password: 651151

Dial by Telephone  
+1 646 558 8656 or +1 406 444 9999  
Meeting ID: 860 0161 0494  
Password: 651151  
Find your local number: <https://mt-gov.zoom.us/j/86001610494>

Join by SIP  
[86001610494@zoomcrc.com](mailto:86001610494@zoomcrc.com)

Join by H.323 (Polycom)  
162.255.37.11##86001610494

Please contact Loryn Johnson at the Department of Environmental Quality at (406) 444-1388 or Loryn.Johnson2@mt.gov should you encounter any difficulties.

2. The department will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact Loryn Johnson, Paralegal, no later than 4:00 p.m. on February 2, 2022, to advise us of the nature of the accommodation that you need. Please contact Loryn Johnson at the Department of Environmental Quality, P.O. Box 200901, Helena, Montana 59620-0901; phone (406) 444-1388; fax (406) 444-4386; or e-mail Loryn.Johnson2@mt.gov.

3. General Reason Statement: Through this rulemaking, the department is proposing to update hazardous waste fees and to incorporate by reference the 2021 version of the federal Resource Conservation and Recovery Act (RCRA) Subtitle C hazardous waste regulations in Title 40 of the Code of Federal Regulations (CFR). The incorporation by reference process is accomplished by amending the CFR publication date specified in ARM 17.53.105(3). The proposed amendments are necessary for the department to maintain consistency with federal RCRA Subtitle C regulations and preserve the state hazardous waste program authorization from the U.S. Environmental Protection Agency (EPA).

There are many provisions in the federal RCRA hazardous waste regulations that are not delegable to state hazardous waste programs. For these provisions, the department has adopted the federal regulation but does not substitute state-specific terms for federal references. By retaining the federal references in the non-delegable provisions, the authority to implement those provisions is left with EPA. Throughout this rulemaking, the department is proposing to amend and/or add new exceptions to its adoption of the federal hazardous waste regulations to ensure the authority to implement non-delegable provisions of the federal regulations is retained with EPA. Two primary examples of non-delegable provisions are those related to the import and export of hazardous waste, as well as provisions relating to the e-manifest system.

Throughout this rulemaking, the department is proposing to rename the smallest hazardous waste generator category from "conditionally exempt small quantity generator" to "very small quantity generator." This proposed change aligns with the federal hazardous waste regulations. EPA renamed this generator category as part of its "Hazardous Waste Generator Improvements Rule," published November 11, 2016, in 81 FR 85732. EPA made this revision to remove confusion regarding the phrase "conditionally exempt." For example, all categories of hazardous waste generators are conditionally exempt from storage facility permit, interim status, and operating requirements, not just the smallest category. In addition, the new term more accurately describes what the category represents. All rules previously applicable to a conditionally exempt small quantity generator apply to a very small quantity generator. See proposed amendments to ARM 17.53.301 for the definition of "very small quantity generator."

4. The rules proposed to be adopted provide as follows:

NEW RULE I ADOPTION OF HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL (40 CFR 260) (1) Except as provided otherwise in [NEW RULE II], the department adopts and incorporates by reference 40 CFR 260, Subpart A, Subpart B, and Subpart C pertaining to General Hazardous Waste Management.

AUTH: 75-10-405, MCA  
IMP: 75-10-405, MCA

REASON: The department is proposing to incorporate by reference the entirety of 40 CFR 260 in NEW RULE I, with exceptions and additions to the incorporation by reference specified in NEW RULES II and III. Under the department's current rules, the department incorporates specific provisions of 40 CFR 260 in ARM Title 17, chapter 53, subchapter 4. By moving to an incorporation by reference format that incorporates the entirety of 40 CFR 260 and then excludes or adds to certain provisions of the incorporated federal regulations, the proposed rules align the format of subchapter 4 with the format of other subchapters in ARM Title 17, chapter 53. Moving to this format streamlines the rules for the regulated community and interested parties and provides clarity as to how and where Montana's rules differ from the federal hazardous waste regulations.

NEW RULE II EXCEPTIONS AND ADDITIONS TO ADOPTION OF HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL (1) In 40 CFR 260.1(b)(1), references to "EPA" are retained. The department has separate rules governing access to information and confidentiality at ARM Title 17, chapter 53, subchapter 2.

(2) In 40 CFR 260.1(b)(4) through (6), references to "EPA" are retained.

(3) 40 CFR 260.2(a) and (b), pertaining to availability of information and confidentiality of information, are not adopted. The department has separate rules governing access to information and confidentiality at ARM Title 17, chapter 53, subchapter 2.

(4) In 40 CFR 260.2(c) and (d), 260.4, and 260.5, references to "EPA" are retained.

(5) The definitions in 40 CFR 260.10 are subject to the provisions of ARM 17.53.301.

(6) 40 CFR 260.20 through 260.23, pertaining to rulemaking petitions, are not adopted. Thus, any reference to petitions under these provisions in 40 CFR 124, 260 through 268, 270, 273, and 279, incorporated by reference by this chapter, are not applicable under the Montana hazardous waste program. See [NEW RULE III] for more information.

AUTH: 75-10-405, MCA  
IMP: 75-10-405, MCA

REASON: As part of its proposed reformatting of ARM Title 17, chapter 53, subchapter 4, the department is proposing several exceptions to the incorporation by

reference of 40 CFR 260 in NEW RULE I. In proposed (1) through (3), which address federal access to information regulations, the department proposes to retain references to EPA. The department has state-specific rules governing access to information and confidentiality at ARM Title 17, chapter 53, subchapter 2. Proposed (3) also provides exceptions for certain non-delegable provisions relating to the federal e-manifest system.

In proposed (2) and (5), the department does not adopt federal regulations relating to delisting petitions. This is not a substantive change to the department's hazardous waste rules; this issue was previously addressed in ARM 17.53.401, which the department is proposing to repeal as part of its reorganization of ARM Title 17, chapter 53, subchapter 4. The department's longstanding practice has been to refer delisting petitions to EPA.

### NEW RULE III NO STATE WASTE DELISTING – FEDERAL PETITION

REQUIRED (1) Waste generators may demonstrate that their wastes do not meet criteria utilized by EPA to list hazardous wastes. A successful petition results in that waste being excluded from regulation as a hazardous waste--often referred to as waste "delisting." Under [NEW RULE II(5)], Montana does not adopt 40 CFR 260.20 through 260.23, relating to rulemaking petitions. Petitions by Montana generators to delist a hazardous waste must be filed with EPA.

AUTH: 75-10-405, MCA

IMP: 75-10-405, MCA

REASON: See reason statement for New Rule II. The department is proposing to retain its longstanding practice to defer delisting petitions to EPA. This proposed rule is not a substantive change to the department's hazardous waste rules, and was previously addressed in ARM 17.53.401, which the department is proposing to repeal as part of its reorganization of ARM Title 17, chapter 53, subchapter 4.

5. The rules proposed to be amended provide as follows, stricken matter interlined, new matter underlined:

17.53.105 INCORPORATION BY REFERENCE (1) and (2) remain the same.

(3) ~~Except as provided in (4), references~~ References in this chapter that incorporate 40 CFR 60, 61, 63, 124, 260 through 268, 270, 273, or 279 refer to the version of that publication revised as of ~~July 1, 2014~~ July 1, 2021. References in this chapter to 40 CFR 124, 260 through 268, 270, 273, or 279 that incorporate publications refer to the version of the publication as specified at 40 CFR 260.11. Provisions within 40 CFR 60, 61, and 63 that are referenced in 40 CFR 124, 260 through 268, 270, 273, or 279 are also incorporated by reference.

~~(4) For the purposes of this chapter, the department does not adopt and incorporates by reference the final rules published in the Federal Register at 73 FR 64668 on October 30, 2008, "Revisions to the Definition of Solid Waste," to be codified at 40 CFR 260, 261, and 270.~~

(5)(4) Copies of the CFR are available from the Superintendent of Documents, U.S. Government Printing Publishing Office Washington, D.C. 20402, (202) 512-1800 --New Orders, P.O. Box 979050, St. Louis, MO 63197-9000, (866) 512-1800. The CFR can also be accessed electronically at "<http://www.access.gpo.gov/nara/cfr/index.html>" <https://www.govinfo.gov/app/collection/cfr>. Materials adopted and incorporated by reference in this chapter are also available for public inspection and copying at the Department of Environmental Quality, 1520 E. 6th Ave., P.O. Box 200901, Helena, MT 59620-0901.

(6) through (8) remain the same but are renumbered (5) through (7).

AUTH: 75-10-405, MCA

IMP: 75-10-405, MCA

**REASON:** The department is proposing to amend ARM 17.53.105 to incorporate by reference the July 1, 2021, version of the Code of Federal Regulations (CFR). The incorporation by reference process is accomplished by amending the CFR publication date specified in (3). The proposed amendment allows the department to maintain consistency with EPA regulations and preserve the state's hazardous waste program authorization.

The department is proposing to delete (4), which excluded from the department's incorporation by reference the federal "Revisions to the Definitions of Solid Waste" rule. By removing the exclusion, the department is proposing to incorporate the current version of these federal regulations, published on May 30, 2018, at 83 FR 24664, into the department's hazardous waste rules. The department is proposing to adopt the 2018 definition of solid waste regulations to ensure regulated entities and the department have a consistent and clear definition of legitimate recycling of hazardous secondary materials. In addition, the 2018 definition of solid waste regulations provide regulatory certainty and a practical framework to promote the legitimate recycling of hazardous secondary materials. Removing roadblocks to legitimate recycling is good for business and the environment, and will result in conserving natural resources, reducing waste, saving energy, and reducing costs.

In proposed new (4), the department is proposing to update the mailing and website address for ordering copies of the CFR.

#### 17.53.107 SUBSTITUTION OF STATE TERMS FOR FEDERAL TERMS

(1) The following terms used in 40 CFR 124, ~~261, 262, 264 through 266, 260 through 268, 270, 273, or 279~~, as adopted and incorporated by reference in this chapter, have the meanings specified below, unless otherwise indicated in these rules:

(a) through (n) remain the same.

~~(2) The definitions of the following terms found in 40 CFR 260.10 are excluded from substitution pursuant to (1)(b) and (j):~~

~~(a) administrator; and~~

~~(b) regional administrator.~~

~~(3)~~(2) The definitions of the following terms found in 40 CFR 260.10 are excluded from substitution pursuant to (1)(b), (e), and (j):

- ~~(a) administrator;~~ Administrator;
- ~~(b) Electronic manifest(or e-Manifest);~~
- ~~(c) Electronic Manifest System (or e-Manifest System);~~
- ~~(b)(d) EPA region; and~~
- ~~(e) Manifest;~~
- ~~(c)(f) regional administrator;~~ Regional Administrator; and
- ~~(g) User of the electronic manifest system.~~

~~(4)~~(3) The substitution of terms in (1) does not apply in the following portions of 40 CFR 260 through 40 CFR 270 268, 270, 273, and 279, as adopted and incorporated by reference in this chapter:

- ~~(a) 40 CFR 260.2(c);~~
- ~~(b) 40 CFR 260.2(d);~~
- ~~(c) 40 CFR 260.4;~~
- ~~(d) 40 CFR 260.5;~~
- ~~(a) through (e) remain the same but are renumbered (e) through (i).~~
- ~~(j) 40 CFR 261.39(a)(5);~~
- ~~(k) 40 CFR 261.41;~~
- ~~(f) and (g) remain the same but are renumbered (l) and (m).~~
- ~~(h)(n) 40 CFR 262.54~~ 40 CFR 262.24(a)(3);
- ~~(i)(o) 40 CFR 262.52~~ 40 CFR 262.25;
- ~~(j) 40 CFR 262.53. See ARM 17.53.602 for more information;~~
- ~~(k) 40 CFR 262.54. See ARM 17.53.602 for more information;~~
- ~~(l) 40 CFR 262.55. See ARM 17.53.602 for more information;~~
- ~~(m) 40 CFR 262.56. See ARM 17.53.602 for more information;~~
- ~~(n) 40 CFR 262.57. See ARM 17.53.602 for more information;~~
- ~~(o) remains the same but is renumbered (p).~~
- ~~(q) 40 CFR 263.20(a)(4)(iv);~~
- ~~(r) 40 CFR 264.12(a);~~
- ~~(p) 40 CFR 264.12(a)(1);~~
- ~~(s) 40 CFR 264.71;~~
- ~~(t) 40 CFR 265.12(a);~~
- ~~(q) 40 CFR 265.12(a)(1);~~
- ~~(u) 40 CFR 265.71;~~
- ~~(v) 40 CFR 267.71(a)(6);~~
- ~~(w) 40 CFR 267.71(d);~~
- ~~(r) through (ab) remain the same but are renumbered (x) through (ah).~~

AUTH: 75-10-405, MCA

IMP: 75-10-405, MCA

REASON: The proposed amendments are necessary to clarify where substitution of state terms does and does not apply to specific portions of the CFR. Certain provisions of the federal hazardous waste regulations are not delegable to state hazardous waste programs. When the department adopts non-delegable federal provisions, it must not replace federal or international references or terms

with state references. By keeping the federal terms in the rule language, the authority for those provisions remains with EPA. This is necessary for the department to maintain consistency with EPA regulations and preserve the hazardous waste state program authorization.

17.53.111 REGISTRATION OF GENERATORS, ~~AND~~ TRANSPORTERS, AND REVERSE DISTRIBUTORS (1) remains the same.

(2) The following persons are not required to register as hazardous waste generators:

(a) ~~conditionally exempt~~ very small quantity generators who are subject to the exclusionary provisions of ~~40 CFR 261.5~~ 40 CFR 262.14, except for those who generate hazardous waste due to an episodic event in accordance with 40 CFR 262, Subpart L;

(b) through (6) remain the same.

(7) A reverse distributor operating under 40 CFR 266, Subpart P must register with the department.

AUTH: 75-10-204, 75-10-404, 75-10-405, MCA

IMP: 75-10-204, 75-10-212, 75-10-214, 75-10-221, 75-10-405, MCA

REASON: The proposed amendments to (2) keep the existing practice of generally not requiring very small quantity generators (formerly conditionally exempt small quantity generators) to register with the department. Very small quantity generators have fewer regulatory obligations because they generate smaller quantities of hazardous waste than small or large quantity generators. Although not required to register with the department, nothing in this rule precludes very small quantity generators from doing so if they choose. Additionally, under certain circumstances, the department registers very small quantity generators into our database in response to enforcement activities, complaints, and inspections.

The department is proposing to require very small quantity generators who generate hazardous waste due to an episodic event to register with the department and pay registration fees. The department has determined it is reasonably necessary to require these generators to register and pay fees to cover staff time and costs necessary to ensure very small quantity generators comply with regulatory requirements associated with episodic events.

The department is proposing (7) to ensure that the department is made aware of reverse distributors operating in Montana. Although reverse distributors would be required to register with the department, they are not generators of hazardous waste and thus would not be subject to fees. See proposed ARM 17.53.113(10).

17.53.112 FACILITY PERMIT FEES: APPLICATION, REISSUANCE, MODIFICATION, AND MAINTENANCE FEES (1) and (2) remain the same.

(3) At the time the permit reissuance process is initiated, the department shall assess a permit reissuance fee. The fees are as follows:

(a) ~~\$15,000~~ \$18,525 for a Class I facility;

(b) ~~\$7,000~~ \$8,645 for a Class II facility; and

(c) ~~\$3,000~~ \$3,700 for a Class III facility.



(4) and (5) remain the same.

(6) The fees for permit modifications at the request of the permittee are as follows:

(a) ~~\$7,200~~ \$8,890 for Class 3 modifications, as listed in 40 CFR 270.42, Appendix I;

(b) ~~\$3,600~~ \$4,450 for Class 2 modifications, as listed in 40 CFR 270.42, Appendix I; and

(c) for Class 1 modifications listed in 40 CFR 270.42, Appendix I:

(i) ~~\$240~~ \$300 for Class 1 modifications listed in A through E of Appendix I; and

(ii) ~~\$1,200~~ \$1,480 for Class 1 modifications listed in F through L of Appendix I; and

(d) remains the same.

(7) The fees for permit modifications initiated by the department, pursuant to 40 CFR 270.41, are as follows:

(a) for modifications, for causes described in 40 CFR 270.41, the fees are as follows:

(i) ~~\$7,200~~ \$8,890 for Class 3 modifications, as listed in 40 CFR 270.42, Appendix I;

(ii) ~~\$3,600~~ \$4,450 for Class 2 modifications, as listed in 40 CFR 270.42, Appendix I; and

(iii) for Class 1 modifications listed in 40 CFR 270.42, Appendix I:

(A) ~~\$240~~ \$300 for Class 1 modifications listed in A through E of Appendix I; and

(B) ~~\$1,200~~ \$1,480 for Class 1 modifications listed in F through L of Appendix I; and

(b) through (10) remain the same.

AUTH: 75-10-404, 75-10-405, 17-10-406, MCA

IMP: 75-10-405, 75-10-406, MCA

**REASON:** The department has determined reasonable necessity exists to generally amend hazardous waste fee rules to establish sufficient fees to enable the department to effectively operate and implement the federal and state regulatory obligations.

The department is proposing to increase the permit reissuance fees in (3) and the permit modification fees in (6) through (7). The department last updated permit reissuance and modification fees in 2009, using the inflation rate on the U.S. Consumer Price Index (US CPI) as the basis of the increase. Similarly, here, the department is proposing to increase hazardous waste permitting fees based on the rate of inflation since 2010. The department has used the US CPI as the basis for determining the inflation index. The United States Bureau of Labor Statistics inflation calculator compounded the inflation index from January 2010 through August 2020. The average rate for the ten-year period was 2 percent per year. As such, the value of \$1,000 in 2009 calculates to \$1,200 in 2020. In proposing the new fee amounts, the department rounded up the inflationary adjustment to the

nearest \$5.00 to aid and simplify calculations for both the regulated community and the department.

The department intends to adjust hazardous waste permit reissuance and modification, generator registration, registration maintenance, and change of activity fees every five years to reflect the change in the U.S. consumer price index for all urban consumers over the five-year period. This fee adjustment framework will provide a consistent and predictable fee structure for the regulated community and a stable revenue stream for the department's Hazardous Waste Program. Future fee adjustments will be implemented through MAPA rulemaking procedures and will include an opportunity for the public to comment on the proposed fee adjustments prior to implementation.

Hazardous waste permits have a term of ten years, with the option of reissuance. Currently, six Montana facilities hold a hazardous waste permit. Each facility would be affected by the proposed fee increases if it chose to apply for permit reissuance. The cumulative amount of the increase to the permit reissuance fees for the six facilities for the five-year period from 2022 to 2027 would be \$8,925.

Modifications to a permit are based on operational and/or regulatory needs of the permittee and the department; therefore, the number of modifications expected during the ten-year permit term is difficult to predict. Based on permit modifications over the last 20 years, the department is estimating it will process five permit modifications during the five-year period from 2022 to 2027. The cumulative amount of the proposed increase to the permit modifications fees for that period would be \$2,880.

17.53.113 REGISTRATION AND REGISTRATION MAINTENANCE FEES:  
FEE ASSESSMENT (1) remains the same.

(2) Concurrent with the submittal of a registration form, a generator shall submit to the department a registration fee of ~~\$225~~ \$270.

(3) The department shall assess an annual registration maintenance fee, as provided in (4), for the following hazardous waste generators:

(a) and (b) remain the same.

(c) ~~a conditionally exempt very small quantity generator, as defined in ARM 17.53.301(2), that has registered with the department and desires to remain registered~~ that generates hazardous waste due to an episodic event in accordance with 40 CFR 262, Subpart L.

(4) The annual registration maintenance fee for a calendar year is ~~\$200~~ \$240 plus a per-ton fee for all regulated hazardous waste generated during the previous calendar year of:

(a) remains the same.

(b) ~~\$20~~ \$25 per ton for all regulated as-generated waste generated during the ~~2014~~ 2021 calendar year and each year thereafter.

(5) through (7) remain the same.

(8) The department shall assess a change of activity fee, as provided in (9), for any generator who notifies the department as:

(a) an episodic generator operating under 40 CFR 262, Subpart L;

(b) a large quantity generator receiving waste from a very small quantity generator consolidating hazardous waste received from a very small quantity generator in accordance with 40 CFR 262.17(f); and

(c) a healthcare facility, as defined in 40 CFR 266.500, notifying that it is operating under 40 CFR 266, Subpart P.

(9) The change of activity fee is \$150 for each notification to the department provided in (8).

~~(8)~~(10) Persons are not required to pay the registration or registration maintenance fees if they are registered only for the purpose of:

(a) and (b) remain the same.

(c) handling used oil; or

(d) conducting a treatability study; or

(e) notifying the department that they are a reverse distributor operating under 40 CFR 266, Subpart P.

(9) and (10) remain the same but are renumbered (11) and (12).

AUTH: 75-10-404, 75-10-405, MCA

IMP: 75-10-405, MCA

REASON: The department has determined reasonable necessity exists to generally amend its hazardous waste generator registration fee rules to establish sufficient funding to effectively operate and implement federal and state regulatory obligations. The department last finalized rules increasing hazardous waste generator registration fees in 2009. As part of that 2009 rulemaking, the department instituted a three-year stepwise increase of the per ton fees in (4) that brought generator registration maintenance fees to their current rates in 2012.

The department is proposing to increase hazardous waste generator registration and registration maintenance fees based on the rate of inflation since 2012. The department used the US CPI as the basis for determining the inflation index. In proposing the new fee amounts, the department rounded up the inflationary adjustment to the nearest \$5.00 to aid and simplify calculations for both the regulated community and the department.

The department is proposing to amend (3)(c), which previously required annual registration fees from very small quantity generators (formerly conditionally exempt small quantity generators) who had registered with the department and desired to remain registered. The proposed change aligns the hazardous waste rules with the department's current practice of not charging registration maintenance fees to registered very small quantity generators. Under the proposed rules, only very small quantity generators who generate hazardous waste due to an episodic event would be assessed registration maintenance fees. The department proposes to incorporate by reference rules that allow a very small quantity generator or a small quantity generator to maintain its existing generator category if, as a result of a planned or unplanned episodic event, the generator would generate a quantity of hazardous waste in a calendar month sufficient to cause the facility to move into a more stringent generator category.

The department has determined that it is reasonably necessary to charge registration maintenance fees to very small quantity generators who generate

hazardous waste as part of an episodic event because (a) those generators would previously have been subject to fees under our rules by changing to a small or large quantity generator; and (b) the fees are necessary to account for the work required by the department to verify compliance with regulatory requirements.

The department is proposing new fees in (8) and (9) related to change of activity notifications required in federal hazardous waste regulations proposed to be incorporated by reference in this rulemaking. As part of the proposed new rules, certain flexibilities are allowed to generators for episodic generation, consolidation of wastes by large quantity generators, and management of hazardous pharmaceutical wastes. To take advantage of these more flexible rules, generators are required to submit a change of activity notification to the department. The department determined it is necessary to assess a fee for these notifications. The \$150 per change of activity notification proposed by the department is commensurate with the time and work for staff to review and process each notification form, and to verify compliance with regulatory requirements. The change of activity fees proposed in (8) and (9) would apply to those hazardous waste generators already registered with the department, including very small quantity generators.

The department intends to adjust hazardous waste permit reissuance and modification, generator registration, registration maintenance, and change of activity fees every five years to reflect the change in the U.S. consumer price index for all urban consumers over the five-year period. This fee adjustment framework will provide a consistent and predictable fee structure for the regulated community and a stable revenue stream for the department's Hazardous Waste Program. Future fee adjustments will be implemented through MAPA rulemaking procedures and will include an opportunity for the public to comment on the proposed fee adjustments prior to implementation.

Businesses potentially affected by the proposed fee increases are small and large quantity generators of hazardous waste, as well as very small quantity generators who generate hazardous waste as part of an episodic event under 40 CFR 262, Subpart L. Other very small quantity generators, hazardous waste transporters, and facilities with corrective action orders on consent are not expected to be affected by the proposed fee increases.

Based on the number of hazardous waste generators registered with the department in fiscal year 2020, the department estimates 196 businesses would be affected by the proposed increase in registration and registration maintenance fees. An estimated 51 businesses would be affected by the proposed change of activity fees. The cumulative amount of increase over a five-year period is estimated to be \$53,130 for the universe of hazardous waste generators.

17.53.301 DEFINITIONS (1) Except where inconsistent with the definitions in (2), the definitions in 40 CFR 260 through ~~40 CFR 270, 268, 270, 273, and 279~~ are hereby adopted and incorporated by reference.

(2) In this chapter, the following terms shall have the meanings or interpretations shown below:

(a) through (d) remain the same.

~~(e) "Conditionally exempt small quantity generator" or "conditionally exempt generator" means a generator of hazardous waste who generates, in a calendar~~

month, no more than 100 kilograms (220 pounds) of hazardous waste, no more than one kilogram (2.2 pounds) of acute hazardous waste, or no more than 100 kilograms (220 pounds) of any residue or contaminated soil, waste, or other debris resulting from the clean up of a spill, into or on any land or water, of acute hazardous waste.

(f) through (q) remain the same but are renumbered (e) through (p).

(q) "Very small quantity generator" means a generator who generates less than or equal to the following amounts in a calendar month:

(i) 100 kilograms (220 pounds) of nonacute hazardous waste;

(ii) 1 kilogram (2.2 pounds) of acute hazardous waste listed in 40 CFR 261.31 or 40 CFR 261.33(e); and

(iii) 100 kilograms (220 pounds) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in 40 CFR 261.31 or 40 CFR 261.33(e).

AUTH: 75-10-405, MCA

IMP: 75-10-405, MCA

REASON: The department is proposing to amend (1) to ensure all relevant definitions from the federal hazardous waste regulations are incorporated into these rules. This is necessary to ensure the state's hazardous waste program maintains consistency with EPA regulations and to preserve the state's hazardous waste program authorization.

The department is proposing to amend (2) to remove the defined term "conditionally exempt small quantity generator" and replace it with "very small quantity generator." The department's proposed definition matches the federal definition in 40 CFR 260.10. See the general reason statement for additional information regarding the proposed change from "conditionally exempt quantity generator" to "very small quantity generator."

#### 17.53.502 EXCEPTIONS AND ADDITIONS TO ADOPTION OF FEDERAL STANDARDS FOR IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

(1) through (4) remain the same.

~~(5) In 40 CFR 261.21(a)(3), "a flammable gas as defined in 49 CFR 173.115(a)" is substituted for "an ignitable compressed gas as defined in 49 CFR 173.300".~~

(5) The following language is substituted for the language in 40 CFR 261.6(c)(2)(iv), adopted and incorporated by reference in ARM 17.53.501: "ARM 17.53.903 (annual reporting requirements)."

~~(6) In 40 CFR 261.21(a)(4), "an oxidizer as defined in 49 CFR 173.127(a)" is substituted for "an oxidizer as defined in 49 CFR 173.151".~~

(7) and (8) remain the same but are renumbered (6) and (7).

AUTH: 75-10-204, 75-10-404, 75-10-405, MCA

IMP: 75-10-203, 75-10-204, 75-10-403, 75-10-405, 75-10-602, MCA

REASON: The department is proposing (5) to address the requirement in Montana law for annual reporting, to be in accordance with ARM 17.53.903.

The department is proposing to delete the former (5) and (6), as the federal provisions referenced are no longer part of the federal hazardous waste regulations.

17.53.602 EXCEPTIONS AND ADDITIONS TO ADOPTION OF FEDERAL STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE (1) In 40 CFR 262.11(c), the reference to "Administrator" is retained. Petitions by Montana generators to delist a hazardous waste must be filed with EPA.

~~(4)(2)~~ In 40 CFR ~~262.11(c)(4)~~ 262.11(d)(1) and (d)(2), pertaining to hazardous waste determination, the phrase "or according to an equivalent method approved by the Administrator under 40 CFR 260.21" is not adopted and incorporated by reference.

~~(3)~~ In 40 CFR 262.18(d), the reference to "biennial report" is replaced with "annual report."

~~(4)~~ In 40 CFR 262.24(a)(3) and 262.25, references to "EPA" are retained.

~~(2)~~ through ~~(5)~~ remain the same but are renumbered ~~(5)~~ through ~~(8)~~.

~~(6)(9)~~ In 40 CFR ~~262.51, 262.52, 262.53, 262.54, 262.56, and 262.57~~ 262.80 through 262.84, pertaining to exports transboundary movements of hazardous waste for recovery or disposal, references to "EPA" are retained.

~~(7)(10)~~ Exception reports required from primary exporters pursuant to 40 CFR ~~262.55~~ 262.83(h) must be filed with EPA and the department.

~~(8)(11)~~ Annual reports required from primary exporters pursuant to 40 CFR ~~262.56~~ 262.83(g) must be filed with EPA and the department.

~~(9)(12)~~ In 40 CFR ~~262.57(b)~~ 262.83(i)(3) and 262.84(h)(4), pertaining to export and import record keeping, the references to the "Administrator" is are retained. The department may also require extensions of record retention times for hazardous waste export records.

~~(10)(13)~~ Conditionally exempt Very small quantity generators are not subject to the requirements of ARM 17.53.603, except for those who generate due to an episodic event in accordance with 40 CFR 262, Subpart L.

~~(11)~~ In 40 CFR 262, Appendix, Item 19, pertaining to the Uniform Hazardous Waste Manifest and instructions, ~~the second paragraph and the list of EPA administrators is not adopted and incorporated by reference. Also, "Montana" is substituted for "authorized States (i.e., those States that have received authorization from the U.S. EPA to administer the hazardous waste program)".~~

AUTH: 75-10-204, 75-10-404, 75-10-405, MCA

IMP: 75-10-204, ~~75-10-225~~, 75-10-405, MCA

REASON: See the general reason statement for the proposed changed language from "conditionally exempt small quantity generator" to "very small quantity generator."

For the proposed amendments and additional language to (13), see the reason statement for ARM 17.53.111(2).

The department is proposing to delete the reference to 75-10-225, MCA, in the implementing statutes, as the statute has been repealed.

17.53.603 ANNUAL REPORT FROM GENERATORS OF HAZARDOUS WASTE (1) and (2) remain the same.

(3) Reporting for exports of hazardous waste is subject to the requirements of 40 CFR ~~262.56~~ 262.83(h) and ARM 17.53.602(10) rather than the requirements of this rule.

(4) A ~~conditionally exempt~~ very small quantity generator, as defined in ARM 17.53.301(2), ~~that has registered with the department and desires to remain registered~~ that has generated hazardous waste due to an episodic event in accordance with 40 CFR 262, Subpart L shall submit an annual report pursuant to ARM 17.53.603(1).

AUTH: 75-10-404, 75-10-405, MCA

IMP: 75-10-405, MCA

REASON: See the general reason statement for the rationale for changing the name from "conditionally exempt small quantity generator" to "very small quantity generator."

The department is proposing to amend (4) to align the hazardous waste rules with the department's current practice of not requiring very small quantity generators (formerly conditionally exempt small quantity generators) to submit an annual report. Under the proposed rules, only very small quantity generators who generate hazardous waste due to an episodic event under 40 CFR 262, Subpart L would be required to submit an annual report for the year in which the episodic event or events took place.

17.53.701 ADOPTION OF FEDERAL STANDARDS APPLICABLE TO TRANSPORTERS OF HAZARDOUS WASTE (40 CFR 263) (1) Except as provided otherwise in ARM ~~17.53.701~~ 17.53.702, the department ~~hereby~~ adopts and incorporates by reference 40 CFR 263, pertaining to requirements for transporters of hazardous waste.

AUTH: 75-10-404, 75-10-405, MCA

IMP: 75-10-405, 75-10-406, MCA

REASON: The proposed change corrects an incorrect internal reference in the department's current rules. The exceptions and additions to the department's adoption of federal standards applicable to transporters of hazardous waste are located at ARM 17.53.702.

17.53.802 EXCEPTIONS AND ADDITIONS TO ADOPTION OF FEDERAL STANDARDS APPLICABLE TO OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES (1) and (2) remain the same.

(3) The requirements in 40 CFR 264.1(g)(1), pertaining to exclusions from the requirements of 40 CFR 264, are replaced with: "The standards set forth in this subchapter do not apply to owners or operators of solid waste management systems licensed by the department pursuant to ARM Title 17, chapter 50, subchapter 5, if

the only hazardous waste the facility treats, stores, or disposes of is excluded from regulation by the requirements for ~~conditionally exempt~~ very small quantity generators in 40 CFR ~~264.5~~ 262.14 as incorporated by reference in ARM 17.53.501(1)."

(4) In 40 CFR 264.12(a)(~~4~~), pertaining to required notices, the references to "EPA" and "Regional Administrator" ~~is~~ are retained.

(5) In 40 CFR 264.71, relating to use of the manifest system, references to EPA are retained.

(5) through (24) remain the same but are renumbered (6) through (25).

AUTH: 75-10-404, 75-10-405, 75-10-406, MCA

IMP: 75-10-405, 75-10-406, MCA

REASON: Proposed (3) amends "conditionally exempt small quantity generator" to "very small quantity generator." See general reason statement.

The proposed amendments to (4) and (5) add additional exceptions to the incorporation by reference of 40 CFR 265 in ARM 17.53.901. These exceptions are necessary to ensure the authority for non-delegable provisions in the federal hazardous waste regulations relating to hazardous waste imports and exports and the e-manifest program is retained with EPA.

17.53.902 EXCEPTIONS AND ADDITIONS TO ADOPTION OF FEDERAL INTERIM STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES (1) through (3) remain the same.

(4) The requirements in 40 CFR 265.1(c)(5) are replaced with: "The standards set forth in this subchapter do not apply to owners or operators of solid waste management systems licensed by the department pursuant to ARM Title 17, chapter 50, subchapter 5, if the only hazardous waste the facility treats, stores, or disposes of is excluded from regulation by the requirements for ~~conditionally exempt~~ very small quantity generators in 40 CFR ~~264.5~~ 262.14, as incorporated by reference in ARM 17.53.501(1)".

(5) In 40 CFR 265.12(a)(~~4~~), pertaining to required notices, the references to "EPA" and "regional administrator" ~~is~~ are retained.

(6) In 40 CFR 265.71, relating to the use of the manifest system, references to EPA are retained.

(6) through (22) remain the same but are renumbered (7) through (23).

AUTH: 75-10-404, 75-10-405, MCA

IMP: 75-10-405, 75-10-406, MCA

REASON: Proposed (4) amends "conditionally exempt small quantity generator" to "very small quantity generator." See general reason statement.

The proposed amendments to (5) and (6) add additional exceptions to the incorporation by reference of 40 CFR 265 in ARM 17.53.901. These exceptions are necessary to ensure the authority for non-delegable provisions in the federal rules



relating to hazardous waste imports and exports and the e-manifest program is retained with EPA.

17.53.1002 EXCEPTIONS AND ADDITIONS TO ADOPTION OF FEDERAL STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTES AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILITIES

(1) through (8) remain the same.

(9) In 40 CFR 266, Subpart P, relating to hazardous waste pharmaceuticals, all references to "biennial report" are replaced with "annual report" and all references to "biennial reporting" are replaced with "annual reporting."

AUTH: 75-10-404, 75-10-405, MCA

IMP: 75-10-405, 75-10-406, MCA

REASON: The department proposes to add (9) to address the requirement in Montana law for annual reporting in accordance with ARM 17.53.603. Healthcare facilities operating under the hazardous waste pharmaceuticals rule at 40 CFR 266, Subpart P, are subject to the annual reporting requirements under state hazardous waste rules.

17.53.1302 EXCEPTIONS AND ADDITIONS TO ADOPTION OF UNIVERSAL WASTE RULE ~~(1) In 40 CFR 273.20(b) and (c), 273.40(b) and (c), and 273.56, pertaining to exporters of universal waste, the term "EPA" is retained.~~

(2) through (4) remain the same but are renumbered (1) through (3).

AUTH: 75-10-405, MCA

IMP: 75-10-404, 75-10-405, MCA

REASON: The department is deleting ARM 17.53.1302(1) because the updated federal regulations cited no longer contain reference to "EPA," making the exception in (1) unnecessary.

6. The rules proposed to be repealed are as follows:

17.53.401 NO STATE WASTE DELISTING - FEDERAL PETITION REQUIRED

AUTH: 75-10-405, MCA

IMP: 75-10-405, MCA

REASON: The department proposes to repeal ARM 17.53.401 through 17.53.403, which currently incorporate by reference specific provisions of 40 CFR 260. In New Rule I, the department is proposing to incorporate by reference the entirety of 40 CFR 260, subject to exceptions in New Rule II, in order to align with the format of other subchapters within ARM Title 17, chapter 53. As such, incorporating these specific federal provisions is no longer necessary. The

proposed rule deletions do not substantively change the existing hazardous waste rules.

17.53.402 ADOPTION OF FEDERAL PROCEDURES FOR VARIANCES FROM CLASSIFICATION AS A WASTE OR BOILER

AUTH: 75-10-405, MCA

IMP: 75-10-405, MCA

REASON: See reason statement for the repeal of ARM 17.53.401.

17.53.403 ADOPTION OF FEDERAL PROCEDURES FOR ADDITIONAL REGULATION OF CERTAIN HAZARDOUS WASTE RECYCLING ACTIVITIES

AUTH: 75-10-405, MCA

IMP: 75-10-405, MCA

REASON: See reason statement for the repeal of ARM 17.53.401.

7. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to: Loryn Johnson, Paralegal, Department of Environmental Quality, 1520 E. Sixth Avenue, P.O. Box 200901, Helena, Montana 59620-0901; faxed to (406) 444-4386; or e-mailed to Loryn.Johnson2@mt.gov, no later than 4:00 p.m., February 14, 2022. To be guaranteed consideration, mailed comments must be postmarked on or before that date.

8. Nicholas Whitaker, attorney for the department, has been designated to preside over and conduct this hearing.

9. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies that the person wishes to receive notices regarding: air quality; hazardous waste/waste oil; asbestos control; water/wastewater treatment plant operator certification; solid waste; junk vehicles; infectious waste; public water supply; public sewage systems regulation; hard rock (metal) mine reclamation; major facility siting; open cut mine reclamation; strip mine reclamation; subdivisions; renewable energy grants/loans; wind energy, wastewater treatment or safe drinking water revolving grants and loans; water quality; CECRA; underground/above ground storage tanks; MEPA; or general procedural rules other than MEPA. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to Loryn Johnson, Paralegal, Department of Environmental Quality, 1520 E. Sixth Ave., P.O. Box 200901, Helena, Montana 59620-0901, faxed to the office at (406) 444-1388, e-mailed to Loryn Johnson at loryn.johnson2@mt.gov, or may be made by completing a request form at any rules hearing held by the department.

10. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

11. With regard to the requirements of 2-4-111, MCA, the department has determined that the adoption, amendment, and repeal of the above-referenced rules will not significantly and directly impact small businesses.

Reviewed by:

DEPARTMENT OF ENVIRONMENTAL  
QUALITY

/s/ Angela Colamaria  
ANGELA COLAMARIA  
Rule Reviewer

/s/ Christopher Dorrington  
CHRISTOPHER DORRINGTON  
Director  
Department of Environmental Quality

Certified to the Secretary of State January 4, 2022.

BEFORE THE BOARD OF PHARMACY  
DEPARTMENT OF LABOR AND INDUSTRY  
STATE OF MONTANA

In the matter of the amendment of	)	NOTICE OF PUBLIC HEARING ON
ARM 24.174.701 pharmacy technician	)	PROPOSED AMENDMENT
registration requirements, 24.174.711	)	
ratio of pharmacy technicians and	)	
interns to supervising pharmacists, and	)	
24.174.712 application for approval of	)	
utilization plan	)	

TO: All Concerned Persons

1. On February 4, 2022, at 10:00 a.m., a public hearing will be held via remote conferencing to consider the proposed amendment of the above-stated rules. There will be no in-person hearing. Interested parties may access the remote conferencing platform in the following ways:

- a. Join Zoom Meeting, <https://mt-gov.zoom.us/j/88393888233>  
Meeting ID: 883 9388 8233, Passcode: 746830  
-OR-
- b. Dial by telephone, +1 406 444 9999 or +1 646 558 8656  
Meeting ID: 883 9388 8233, Passcode: 746830

The hearing will begin with a brief introduction by department staff to explain the use of the videoconference and telephonic platform. All participants will be muted except when it is their time to speak.

2. The Department of Labor and Industry (department) will make reasonable accommodations for persons with disabilities who wish to participate in this public hearing or need an alternative accessible format of this notice. If you require an accommodation, contact the Board of Pharmacy no later than 5:00 p.m., on January 28, 2022, to advise us of the nature of the accommodation that you need. Please contact Marcie Bough, Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; telephone (406) 841-2371; Montana Relay 711; facsimile (406) 841-2305; or [dlibsdpba@mt.gov](mailto:dlibsdpba@mt.gov) (board's e-mail).

3. GENERAL REASON: The board determined it is reasonably necessary to amend three rules regarding pharmacy staffing to remove the 1:4 pharmacist to pharmacy technician ratio, change technician utilization plan requirements, and recognize use of other health care licensees in vaccine administration.

The amendments recognize provisions implemented through the board's emergency rule, MAR Notice No. 24-174-77, effective September 14, 2021, that waived the ratio for purposes of administering COVID-19 vaccines and tests and other vaccines and allowed other health care licensees to assist pharmacists in vaccine administration if authorized within their own scopes of practice. The emergency rule implemented provisions similar to those in Governor Greg

Gianforte's March 2021 directive that expired June 30, 2021, with the end of the COVID-19 state of emergency. Because the emergency rule will expire January 11, 2022, the board determined these changes are reasonably necessary to make permanent the provisions of the directive and emergency rule as requested by pharmacy stakeholders to address pharmacy staffing shortages and accommodate the increasing number of patients seeking COVID-19 and flu vaccines.

While the board did amend the ratio in 2019 (MAR Notice No. 24-174-71) from 1:3 to 1:4 and removed pharmacy interns from counting against the ratio, the proposed amendments build on past discussions and also address ongoing requests from pharmacy stakeholders to remove the ratio as has happened in 23 other states.

The board reviewed other states' requirements for specific ratios or lack of ratios, and considered pharmacy stakeholders' input. Noting that the board has received neither patient safety nor other complaints based on the ratio waiver, the board determined it is reasonably necessary to remove the technician ratio while emphasizing pharmacist-in-charge oversight and responsibility in pharmacy staffing to ensure patient safety and compliance with technician utilization plans. Further, removing the ratio will ensure continued vaccine access while allowing pharmacists more time to focus on patient care services and better utilizing the evolving role of pharmacy technicians for other authorized duties.

The board recognizes that currently pharmacy technicians have federal, not state, authority to assist pharmacists in vaccine administration and tests per the Public Readiness and Emergency Preparedness Act (PREP Act, Public Law 109-148). The PREP Act and corresponding declarations authorize pharmacists to independently order and administer authorized COVID-19 vaccines, other vaccines, and COVID-19 tests. The PREP Act also allows interns and qualified pharmacy technicians, who meet certain training requirements and operate under pharmacist supervision, to administer COVID-19 vaccines and tests and other vaccines. For reference, the board also recognizes that Montana pharmacists have independent authority to order and administer certain vaccines without a collaborative practice agreement, pursuant to 37-7-105, MCA, and ARM 24.174.501, and can utilize interns to assist in administering vaccines.

4. The rules proposed to be amended are as follows, stricken matter interlined, new matter underlined:

24.174.701 PHARMACY TECHNICIAN REGISTRATION REQUIREMENTS

(1) through (1)(f) remain the same.

(i) The board recognizes other Montana health care licensing boards as certifying entities for which licensees can assist the pharmacist(s) in administering vaccines, in compliance with state and federal requirements, under the supervision of a pharmacist, pursuant to the following restrictions:

(A) The health care licensee is in good standing with their licensing board and is authorized to administer vaccines under their own scope of practice. The health care licensee does not need a separate pharmacy technician license issued by the board.

(B) The pharmacist(s) is authorized to prescribe, dispense, and administer vaccines, pursuant to 37-7-105, MCA, and ARM 24.174.503, and in compliance with state and federal requirements.

(ii) The technician utilization plan must reflect use of health care licensees to assist pharmacists in administration of vaccines as authorized in (i) and their license must be conspicuously displayed at the pharmacy.

(2) remains the same.

(3) No pharmacist, ~~or intern, or health care licensee~~ whose license has been denied, revoked, ~~or is currently suspended~~, or restricted for disciplinary purposes shall be eligible to be registered as a pharmacy technician.

AUTH: 37-1-131, 37-7-201, MCA

IMP: 37-1-305, 37-7-201, MCA

REASON: The board is amending this rule to recognize other Montana health care licensing boards as board-approved certifying entities and allow licensees with vaccine administration authority under their own scopes of practice to assist in vaccine administration. The board recognizes the success of pharmacists utilizing other licensees as authorized in the directive and emergency rules and notes that the assisting health care licensees will not need a separate license from the board, but the technician utilization plan must reflect such services.

24.174.711 RATIO OF PHARMACY TECHNICIANS AND INTERNS TO SUPERVISING PHARMACISTS (1) ~~A registered pharmacist in good standing may supervise the services of no more than four pharmacy technicians at any time. The 1:4 pharmacist to pharmacy technician ratio may be revised by the board at any time for good cause. The ratio of pharmacy technicians to pharmacist(s) on duty is to be determined by the pharmacist-in-charge.~~ A pharmacist intern does not count against the pharmacist to pharmacy technician ratio.

(2) ~~Registered pharmacists in good standing in the state of Montana may supervise a maximum of four registered pharmacy technicians~~ The pharmacist-in-charge will ensure that the number of pharmacy technicians on duty can be satisfactorily supervised by the pharmacist(s) on duty to ensure patient safety and a safe work environment, provided:

(a) in the professional judgment of the pharmacist on duty, the ratio and supervision of pharmacy technicians is adequate and manageable based on the technician's scope of practice, education, skill and experience, the policy and procedures of the pharmacy must allow for safe and accurate filling and labeling of prescriptions, and the ratio must be assessed with regard to the pharmacy's quality assurance program, pursuant to ARM 24.174.407;

(b) a technician utilization plan, as described in ARM 24.174.712, must include the policy and procedures and shall be reviewed annually. All affected supervising pharmacists and pharmacy technicians must be familiar with the contents and any changes made must be reported to the board; and

(c) a copy of the policy and procedures must be available for inspection by the board compliance officer.

~~(3) If a pharmacy desires more than four technicians to work under the~~

~~supervision, direction, and control of one pharmacist, the pharmacy shall obtain the prior written approval of the board. To apply for approval, the pharmacist-in-charge shall submit a pharmacy services plan to the board. The pharmacy services plan submitted shall demonstrate how the plan facilitates the provision of pharmaceutical care and shall include, but shall not be limited to the following:~~

- ~~(a) design and equipment;~~
- ~~(b) information systems;~~
- ~~(c) work flow; and~~
- ~~(d) quality assurance procedures.~~

~~(4) The board shall grant approval of a pharmacy service plan only when the board is satisfied that the provision of pharmaceutical care by the pharmacy will be enhanced by the increased use of technicians. An exception may be revoked by the board at any time for good cause.~~

~~(5) (3) No pharmacy shall modify a board-approved pharmacy service plan technician utilization plan without the prior written approval of the board.~~

~~(6) Nothing in this rule shall prevent a pharmacy from terminating a service plan upon written notification to the board.~~

AUTH: 37-7-201, MCA

IMP: 37-7-101, 37-7-201, 37-7-307, 37-7-308, 37-7-309, MCA

REASON: The board is amending this rule to eliminate the 1:4 pharmacist to technician ratio. Following the amendment, patient and work environment safety will be ensured when the pharmacist-in-charge sets staffing ratios on duty, so the number of technicians (ratio) and supervision is adequate and manageable based on the technicians' scopes of practice, education, skill, and experience.

To align with the elimination of the ratio and the inclusion of a pharmacy's staffing ratio in the technician utilization plans, the board will no longer need to approve ratio variances. The board is striking (6) as unnecessary since all utilization plan changes, including termination must be board approved per (3).

24.174.712 APPLICATION FOR APPROVAL OF UTILIZATION PLAN (1) A registered pharmacist in good standing in the state of Montana The pharmacist-in-charge may apply to the board for ~~permission approval~~ to use the services of a pharmacy technician, including the use of authorized health care licensees, as described in ARM 24.174.701(1)(f), to assist pharmacists in the administration of vaccines, in compliance with state and federal requirements, by submitting to the board:

- (a) remains the same.
- (b) a summary of the technician utilization plan, to include information showing compliance with all requirements set forth in these rules, plus all other requirements of 37-7-307, 37-7-308, and 37-7-309, MCA, and this chapter;
- (c) the appropriate fee for initial approval of the technician utilization plan;
- (d) any changes in the technician utilization plan, including technician training and use of other health care licensees for administration of vaccines, as described in ARM 24.174.701(1)(f), must be resubmitted to the board for approval before implementation of the changes by the supervising pharmacist.

(2) Any number of registered pharmacists employed in the same pharmacy may sign as supervising pharmacist of a pharmacy technician on a single technician utilization plan submitted for approval to the board by that pharmacy.

(3) A ~~registered pharmacist in good standing in the state of Montana~~ pharmacist-in-charge may apply to the board to designate that pharmacy as a technician training site for a board-approved academic program curriculum. If the pharmacy training site does not have an approved technician utilization plan in place, the pharmacy may substitute an academic program training plan, assessment criteria and periodic contact plan for board approval, for the purpose of providing on-the-job experience for technician trainees.

(4) A technician utilization plan must be available for inspection by the board.

AUTH: 37-7-201, MCA

IMP: 37-7-201, 37-7-308, 37-7-309, MCA

REASON: The board is amending the technician utilization plan requirements to reflect removal of the ratio and inclusion of other health care licensees for vaccine administration. With the shift of additional responsibility to the pharmacist-in-charge regarding ratio, the board determined it is reasonably necessary for the pharmacist-in-charge to also be the single point of communication for submitting and updating technician utilization plans.

5. Concerned persons may present their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513, by facsimile to (406) 841-2305, or e-mail to [dlibsdp@mt.gov](mailto:dlibsdp@mt.gov), and must be received no later than 5:00 p.m., February 11, 2022.

6. An electronic copy of this notice of public hearing is available at [www.pharmacy.mt.gov](http://www.pharmacy.mt.gov) (department and board's website). Although the department strives to keep its websites accessible at all times, concerned persons should be aware that websites may be unavailable during some periods, due to system maintenance or technical problems, and that technical difficulties in accessing a website do not excuse late submission of comments.

7. The board maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this board. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies that the person wishes to receive notices regarding all board administrative rulemaking proceedings or other administrative proceedings. The request must indicate whether e-mail or standard mail is preferred. Such written request may be sent or delivered to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; faxed to the office at (406) 841-2305; e-mailed to [dlibsdp@mt.gov](mailto:dlibsdp@mt.gov); or made by completing a request form at any rules hearing held by the agency.



8. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

9. Regarding the requirements of 2-4-111, MCA, the board has determined that the amendment of ARM 24.174.701, 24.174.711, and 24.174.712 will not significantly and directly impact small businesses.

Documentation of the board's above-stated determination is available upon request to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; telephone (406) 841-2371; facsimile (406) 841-2305; or to dlibsdp@mt.gov.

10. Department staff has been designated to preside over and conduct this hearing.

BOARD OF PHARMACY  
TONY KING, RPh  
PRESIDENT

/s/ DARCEE L. MOE  
Darcee L. Moe  
Rule Reviewer

/s/ LAURIE ESAU  
Laurie Esau, Commissioner  
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State January 4, 2022.

BEFORE THE DEPARTMENT OF REVENUE  
OF THE STATE OF MONTANA

In the matter of the amendment of ) NOTICE OF PROPOSED  
ARM 42.12.503 pertaining to ) AMENDMENT  
competitive bid form requirements )  
 ) NO PUBLIC HEARING  
 ) CONTEMPLATED

TO: All Concerned Persons

1. The Department of Revenue (department) proposes to amend the above-stated rule.

2. The department will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, please advise the department of the nature of the accommodation needed, no later than 5 p.m. on January 21, 2022. Please contact Todd Olson, Department of Revenue, Director's Office, P.O. Box 7701, Helena, Montana 59604-7701; telephone (406) 444-7905; fax (406) 444-3696; or todd.olson@mt.gov.

3. The rule as proposed to be amended provides as follows, new matter underlined, deleted matter interlined:

42.12.503 RETAIL ALCOHOLIC BEVERAGE LICENSE COMPETITIVE BID FORMS (1) through (3) remain the same.

(4) A bidder will be disqualified from the competitive bidding process if:

(a) through (d) remain the same.

(e) the irrevocable letter of credit fails to identify the department as the beneficiary; or

(f) the irrevocable letter of credit is not equal to or greater than the bidder's bid amount; or

~~(g) the irrevocable letter of credit fails to specify the license type and quota area.~~

AUTH: 16-1-303, 16-4-105, 16-4-201, 16-4-204, 16-4-420, MCA

IMP: 16-4-105, 16-4-201, 16-4-204, 16-4-401, 16-4-420, 16-4-430, MCA

REASONABLE NECESSITY: In the department's review of its administrative rules for the Governor's Red Tape Relief Initiative, the department observes that the failure of an alcoholic beverage license competitive bid applicant to meet the requirement stated in (4)(g) is a common reason for bid disqualification and is often outside of the applicant's direct control. The department proposes to amend the rule to remove this requirement which will improve the competitive bid process by reducing regulatory burden for competitive bid applicants and will increase the number of successful alcoholic beverage license competitive bids.

4. Concerned persons may submit their data, views, or arguments concerning the proposed action, in writing, to Todd Olson, Department of Revenue, Director's Office, P.O. Box 7701, Helena, Montana 59604-7701; telephone (406) 444-7905; fax (406) 444-3696; or e-mail [todd.olson@mt.gov](mailto:todd.olson@mt.gov) and must be received no later than February 14, 2022.

5. If persons who are directly affected by the proposed action wish to express their data, views, or arguments orally or in writing at a public hearing, they must make written request for a hearing and submit this request along with any written comments to the person named in #4 no later than February 14, 2022.

6. If the agency receives requests for a public hearing on the proposed action from either 10 percent or 25, whichever is less, of the persons directly affected by the proposed action; from the appropriate administrative rule review committee of the Legislature; from a governmental subdivision or agency; or from an association having not less than 25 members who will be directly affected, a hearing will be held at a later date. Notice of the hearing will be published in the Montana Administrative Register. The number of hearing requests necessary for the department to conduct a public hearing is 12, which is approximately 10 percent of the number of licenses and competitive bid applicants impacted by these rule changes.

7. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a different mailing preference is noted in the request. Such written request may be mailed or emailed to the contact person in #4.

8. An electronic copy of this notice is available through the Secretary of State's web site at [sosmt.gov/arm/register](http://sosmt.gov/arm/register).

9. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

10. With regard to the requirements of 2-4-111, MCA, the department has determined that the amendment of the above-referenced rule will not significantly and directly impact small businesses.

/s/ Todd Olson  
Todd Olson  
Rule Reviewer

/s/ David R. Stewart  
David R. Stewart  
Authorized Signor  
for the Department of Revenue

Certified to the Secretary of State January 4, 2022.

BEFORE THE STATE LOTTERY AND SPORTS WAGERING COMMISSION  
DEPARTMENT OF ADMINISTRATION  
OF THE STATE OF MONTANA

In the matter of the amendment of ARM ) NOTICE OF AMENDMENT  
2.63.203, 2.63.401, 2.63.403, 2.63.407, )  
2.63.611, and 2.63.1201 pertaining to )  
definitions, places of sale, applications )  
and fees, commission, revocation or )  
suspension of license, and prizes )

TO: All Concerned Persons

1. On November 5, 2021, the State Lottery and Sports Wagering Commission published MAR Notice No. 2-63-621 pertaining to the proposed amendment of the above-stated rules at page 1441 of the 2021 Montana Administrative Register, Issue Number 21. On November 19, 2021, the commission published an amended notice at page 1569 of the 2021 Montana Administrative Register, Issue Number 22, that provided proper notice to the appropriate legislative interim committee without changing the substance of the proposed amendments.

2. All comments received concerned the proposed amendment of ARM 2.63.407. The commission has thoroughly considered the comments received. The comments received are summarized as follows with responses from the commission:

Comment #1: One commenter expressed support for the proposed amendment of ARM 2.63.407 to allow the State Lottery and Sports Wagering Commission to lower the commissions of sports wagering sales agents as part of a broader reset of commissions to reduce the overall cost to consumers of participating in sports wagering. The commenter mentioned complaints that the cost of sports wagering exceeded the price some consumers were willing to pay.

Response #1: The commission appreciates the comment and agrees it is necessary for the commission, its vendor, and sales agents to reduce their fees to decrease the cost of sports wagering for consumers and to make the sports wagering products offered by the lottery and its sales agents more competitive with sports wagering products offered by others.

Comment #2: A commenter recommended that all parties involved in sports wagering through the lottery receive comparable reductions in their commission percentages. The commenter further requested that the rule provide parameters for changing sales agent commissions and setting a minimum percentage or floor for such commissions.

Response #2: The commission agrees that all parties should reduce current sports wagering fees to decrease the cost to consumers. The commission also

agrees it is appropriate to establish parameters to ensure future commission changes are fair and equitable. The commission has amended the rule accordingly and added language to reflect the commission's intent to provide notice and an opportunity for public comment prior to adjusting sales agent fees. The lottery considered setting a minimum commission percentage but ultimately decided not to set a floor to allow the lottery more flexibility to adjust fees when necessary to address changes in the highly competitive and dynamic sports wagering market.

Comment #3: One commenter cautioned that the proposed amendment of ARM 2.63.407 may violate the rulemaking requirements of the Montana Administrative Procedure Act (MAPA) and the provisions of 23-7-202 and 23-7-301, MCA. The commenter suggested that rulemaking was required whenever the State Lottery and Sports Wagering Commission proposed to adjust sales agent fees and that the statutes in Title 23, chapter 7, MCA require sales agent commissions be set by rule.

Response #3: The commission respectfully disagrees. The commission believes it has satisfied the requirements of MAPA through this rulemaking process. Under 23-7-202(10), MCA, the commission is required to "adopt rules relating to lottery and sports wagering and sales agents' commissions." Section 23-7-301(10), MCA, allows the lottery to "adopt rules providing additional commissions to sales agents based on incremental sales." Neither statute requires the lottery to fix the amount or percentage of sales agents' commissions in rule. Instead, the statutes allow the lottery to adopt rules relating to sales agents' commissions, and in accordance with the rulemaking authority granted by the legislature, the lottery has amended ARM 2.63.407 to specify in rule how sales agents' commissions will be established and the parameters for doing so.

3. The department has amended the following rules as proposed: ARM 2.63.203, 2.63.401, 2.63.403, 2.63.611, and 2.63.1201.

4. The department has amended the following rule as proposed, but with the following changes from the original proposal, new matter underlined, deleted matter interlined:

2.63.407 SALES AGENT COMMISSION (1) through (5) remain as proposed.

(6) The sales agent commission for sports wagers will be set by the State Lottery and Sports Wagering Commission. Prior to changing the sales agent base commission rate for sports wagers, the State Lottery and Sports Wagering Commission shall:

(a) provide notice of the proposed change and opportunity for public comment;

(b) consider the impact of the proposed change on sales agents, the state, and other parties involved in the operation of sports wagering; and

(c) ensure the proposed change is equitable and does not disproportionately impact or burden sales agents, the state, and other parties involved in the operation of sports wagering.

By: /s/ Leo Prigge  
Leo Prigge, Acting Chair  
State Lottery and  
Sports Wagering Commission

By: /s/ Don Harris  
Don Harris, Rule Reviewer  
Department of Administration

Certified to the Secretary of State January 4, 2022.

BEFORE THE COMMISSIONER OF SECURITIES AND INSURANCE  
OFFICE OF THE MONTANA STATE AUDITOR

In the matter of the amendment of	)	NOTICE OF AMENDMENT AND
ARM 6.6.2102 pertaining to rates and	)	REPEAL
premiums, and the repeal of ARM	)	
6.6.2103 pertaining to payment or	)	
benefits	)	

TO: All Concerned Persons

1. On November 19, 2021, the Commissioner of Securities and Insurance, Office of the Montana State Auditor (CSI) published MAR Notice No. 6-266 pertaining to the proposed amendment and repeal of the above-stated rules at page 1573 of the 2021 Montana Administrative Register, Issue Number 22.

2. The CSI has amended the above-stated rule as proposed.

3. The CSI has repealed the above-stated rule as proposed.

4. The CSI has thoroughly considered the comments received. A summary of the comments received and CSI's responses are as follows:

COMMENT 1: One commenter stated that he was against the elimination of the prohibition against using sex or marital status as a basis for establishing insurance premium rates.

RESPONSE 1: The CSI's proposed rule changes do not propose the elimination of the prohibition. The prohibition was eliminated by the 67th Legislature's House Bill 379, which amended 49-2-309, MCA, effective January 1, 2022. The CSI's proposed rule changes bring the department's rules in line with the amended statute.

COMMENT 2: One commenter asked who is proposing this amendment and repeal of elements of ARM 6.6.2102 and 6.6.2103.

RESPONSE 2: The CSI is proposing the rule changes to bring its rules in line with the 67th Legislature's House Bill 379, which amended 49-2-309, MCA, effective January 1, 2022.

/s/ Richard E. Wootton  
Richard E. Wootton  
Rule Reviewer

/s/ Ole Olson  
Ole Olson  
Chief Legal Counsel  
Commissioner of Securities and Insurance,  
Office of the Montana State Auditor

Certified to the Secretary of State January 4, 2022.

BEFORE THE BOARD OF PUBLIC EDUCATION  
OF THE STATE OF MONTANA

In the matter of the amendment of ) NOTICE OF AMENDMENT  
ARM 10.54.1010 pertaining to the )  
transformation learning program )

TO: All Concerned Persons

1. On November 19, 2021, the Board of Public Education (board) published MAR Notice No. 10-54-291 pertaining to the proposed amendment of the above-stated rule at page 1576 of the 2021 Montana Administrative Register, Issue Number 22.

2. The board has amended the above-stated rule as proposed.

3. The board has thoroughly considered the comments and testimony received. A summary of the comment received, and the board's response is as follows:

COMMENT #1: Abigail St. Lawrence, counsel, representing the Montana Association for Gifted and Talented Education (AGATE), requested the application window be extended one week from January 10, 2022, to January 17, 2022.

RESPONSE #1: The board thanks Ms. St. Lawrence and the Association for Gifted and Talented Education (AGATE) for their comment. The board recognizes the small window for submission this year, but notes that the Office of Public Instruction (OPI) has made the application available on the OPI website to be downloaded and completed and that the window is for submission of the application. This information has been made available to districts well in advance of the deadline of January 10, 2022.

/s/ McCall Flynn  
McCall Flynn  
Rule Reviewer

/s/ Tammy Lacey  
Tammy Lacey  
Chair  
Board of Public Education

Certified to the Secretary of State January 4, 2022.



BEFORE THE DEPARTMENT OF FISH, WILDLIFE AND PARKS  
OF THE STATE OF MONTANA

In the matter of the adoption of	)	NOTICE OF ADOPTION OF
emergency rules closing the Ennis	)	EMERGENCY RULES
Fishing Access Site and the Valley	)	
Garden Fishing Access Site in	)	
Madison County	)	

TO: All Concerned Persons

1. The Department of Fish, Wildlife and Parks (department) has determined the following reasons justify the adoption of emergency rules closing the Ennis Fishing Access Site and the Valley Garden Fishing Access Site:

(a) There are ice jams on the Madison River that have caused water to channel and flood multiple portions of the fishing access sites.

(b) The combination of dangerous conditions includes changing flooded areas throughout the sites, moving ice and debris, and potentially unstable trees that could fall, rendering unsafe conditions for pedestrian and vehicle travel.

(c) Persons recreating at the fishing access sites would be at risk of injury or drowning.

(d) Therefore, as this situation constitutes an imminent peril to public health, safety, and welfare, due to the combination of unsafe conditions and this threat cannot be averted or remedied by any other administrative act, the department adopts the following emergency rules. The emergency rules will be sent as a press release to newspapers throughout the state. Also, signs informing the public of the closures will be posted at access points. The rules will be sent to interested parties, and published as emergency rules in Issue No. 1 of the 2022 Montana Administrative Register.

2. The department will make reasonable accommodations for persons with disabilities who wish to participate in the rulemaking process and need an alternative accessible format of the notice. If you require an accommodation, contact the department no later than 5:00 p.m. on January 28, 2022, to advise us of the nature of the accommodation that you need. Please contact Jessica Snyder, Fish, Wildlife and Parks, 1420 East Sixth Avenue, P.O. Box 200701, Helena, MT 59620-0701; telephone (406) 444-9785; or e-mail [jesssnyder@mt.gov](mailto:jesssnyder@mt.gov).

3. The emergency rules are effective December 30, 2021, when this rule notice is filed with the Secretary of State.

4. The text of the emergency rules provides as follows:

**RULE I ENNIS FISHING ACCESS SITE EMERGENCY CLOSURE** (1) The Ennis Fishing Access Site is located along the Madison River in Madison County.

(2) The Ennis Fishing Access Site is closed to all public occupation and recreation as signed.

(3) This rule will remain in effect until the department determines that the site is again safe for public occupancy. This will depend on the extent and duration of the ice jams on the river causing flooding into the fishing access site. Signs closing the fishing access site will be removed when the rule is no longer effective.

AUTH: 2-4-303, 87-1-202, MCA  
IMP: 2-4-303, 87-1-202, MCA

RULE II VALLEY GARDEN FISHING ACCESS SITE EMERGENCY CLOSURE (1) The Valley Garden Fishing Access Site is located along the Madison River in Madison County.

(2) The Valley Garden Fishing Access Site is closed to all public occupation and recreation as signed.

(3) This rule will remain in effect until the department determines that the site is again safe for public occupancy. This will depend on the extent and duration of the ice jams on the river causing flooding into the fishing access site. Signs closing the fishing access site will be removed when the rule is no longer effective.

AUTH: 2-4-303, 87-1-202, MCA  
IMP: 2-4-303, 87-1-202, MCA

5. The rationale for the emergency rules is set forth in paragraph 1.

6. Concerned persons are encouraged to submit their comments to the department. They should submit their comments along with their names and addresses to: Jessica Snyder, Fish, Wildlife and Parks, 1420 East Sixth Avenue, P.O. Box 200701, Helena, MT 59620-0701; or e-mail [jesssnyder@mt.gov](mailto:jesssnyder@mt.gov). Any comments must be received no later than February 18, 2022.

7. The department maintains a list of interested persons who wish to receive notice of rulemaking actions proposed by the department. Persons who wish to have their name added to the list shall make written request that includes the name and mailing address of the person to receive the notice and specifies the subject or subjects about which the person wishes to receive notice. Such written request may be mailed or delivered to Fish, Wildlife and Parks, Legal Unit, P.O. Box 200701, 1420 East Sixth Avenue, Helena, MT 59620-0701, or may be made by completing the request form at any rules hearing held by the department.

8. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

9. The special notice requirements of 2-4-303, MCA, have been met. All committee members and staff of the Environmental Quality Council, with addresses provided on the Montana Legislature's website ([leg.mt.gov](http://leg.mt.gov)), were contacted by e-mail on December 30, 2021.

/s/ Hank Worsech

Hank Worsech

Director

Department of Fish, Wildlife and Parks

/s/ Kevin Rechkoff

Kevin Rechkoff

Rule Reviewer

Certified to the Secretary of State December 30, 2021.

BEFORE THE DEPARTMENT OF JUSTICE  
OF THE STATE OF MONTANA

In the matter of the amendment of	)	NOTICE OF AMENDMENT AND
ARM 23.16.101, 23.16.116,	)	REPEAL
23.16.117, 23.16.118. 23.16.119,	)	
23.16.301, 23.16.508, 23.16.1703,	)	
23.16.1704, 23.16.1705, 23.16.1713,	)	
23.16.1714, 23.16.1802, 23.16.1901,	)	
23.16.1904, 23.16.1911, 23.16.1918,	)	
23.16.1920, 23.16.1922, 23.16.1931,	)	
and 23.16.3501 pertaining to transfer	)	
of interest among licensees, transfer	)	
of interest to new owners, shake-a-	)	
day games, changes in managers,	)	
sports pools and sports tabs,	)	
Electronic Player Rewards Systems,	)	
and procedure on VGM malfunction	)	
and the repeal of ARM 23.16.2115	)	
pertaining to the use of AARS data	)	
for player tracking	)	

TO: All Concerned Persons

1. On November 5, 2021, the Department of Justice published MAR Notice No. 23-16-260, pertaining to the public hearing on the proposed amendment and repeal of the above-stated rules, at page 1449 of the 2021 Montana Administrative Register, Issue Number 21.

2. The department has amended ARM 23.16.101, 23.16.116, 23.16.118. 23.16.119, 23.16.301, 23.16.508, 23.16.1703, 23.16.1704, 23.16.1705, 23.16.1713, 23.16.1714, 23.16.1901, 23.16.1911, 23.16.1920, 23.16.1922, 23.16.1931, and 23.16.3501, and repealed 23.16.2115 as proposed.

3. The department has amended the following rules as proposed, but with the following changes from the original proposal, new matter underlined, deleted matter interlined:

23.16.117 TRANSFER OF INTEREST TO NEW OWNER (1) through (8) remain as proposed.

(9) Transfers of control of a licensed gambling operation into a receivership, trust, an estate mandated by court order, or to an attorney in fact actually exercising control under a power of attorney require an amended application to be filed. The transfer of ownership interest to an estate that results from the death of a licensee may be reported on Form 37.

(a) through (10) remain as proposed.

AUTH: 23-5-112, 23-5-115, MCA  
IMP: 23-5-115, 23-5-118, 23-5-176, MCA

23.16.1802 DEFINITIONS (1) through (8) remain as proposed.

(9) "EPRS" (electronic player rewards system) means a stand-alone system that electronically acquires information from VGMs ~~to be used for any purpose for the purpose of player rewards, as~~ authorized by Title 23, chapter 5, MCA.

(10) through (31) remain as proposed.

AUTH: 23-5-115, 23-5-602, 23-5-621, MCA

IMP: 23-5-111, 23-5-112, 23-5-115, 23-5-151, 23-5-602, 23-5-603, 23-5-607, 23-5-608, 23-5-610, 23-5-611, 23-5-612, 23-5-621, 23-5-637, MCA

23.16.1904 PROCEDURE ON DISCOVERY OF SUSPECTED OR CONFIRMED VGM MALFUNCTION (1) through (3) remain as proposed.

(4) VGM manufacturers must report software or hardware malfunctions on a completed Form 50A supported by all required documents. The Form 50A and supporting documents must be submitted to the department within 24 hours of the malfunction being ~~reported to, or identified~~ confirmed by, the VGM manufacturer.

(5) and (6) remain as proposed.

AUTH: 23-5-115, 23-5-608, 23-5-621, MCA

IMP: 23-5-602, 23-5-607, 23-5-608, 23-5-616, 23-5-621, MCA

23.16.1918 TESTING FEES (1) Each person submitting an EPRS capable of interfacing with a VGM, VGM, AARS, or CTVS, or a modification to an approved EPRS capable of interfacing with a VGM, VGM, AARS, or CTVS for testing and department approval must:

(a) through (3) remain as proposed.

AUTH: 23-5-115, 23-5-621, MCA

IMP: 23-5-631, 23-5-637, MCA

4. The department conducted a public hearing on November 29, 2021, on the proposed amendment and repeal and accepted comments through 5:00 p.m., December 29, 2021. The department has thoroughly considered the comments received at the public hearing and those timely submitted in writing. A summary of the comments received and the department's response follows:

COMMENT #1: An attorney, whose practice is centered on gambling and liquor licensees, business transactions, and estate planning, commented the proposed amendment to ARM 23.16.117, regarding powers of attorney, is overbroad. The commenter advised the amended rule could negatively impact many business owners whose routine estate plan includes a power of attorney which may never be used on the gambling operation. The commenter observed virtually all estate plans include a power of attorney. As proposed, the rule could be read to transfer an

ownership interest upon the licensee's execution of a power of attorney—even if that power of attorney is never employed to exercise control of the gambling operation.

RESPONSE #1: The department's intent for the proposed amendment was to include transfers of control under powers of attorney in the same general classification as transfers of control through court-ordered receiverships, trusts, or estates. The commenter's remarks are valid in that a power of attorney is a planned device which is prepared against an event (e.g., accident or serious illness) which may never occur so no transfer of control will occur. By contrast, transfers of control mandated by court order are not part of any individual's or business' preplanning and in every case will result in a stranger to the license assuming control. The proposed amendment will be improved by language limiting its application to attorneys in fact actually exercising control under a power of attorney. If a power of attorney does not result in the attorney in fact actually exercising control of a licensed gambling operation the department does not view ARM 23.16.117 to apply. If, however, an attorney in fact does apply his or her authority under a power of attorney there has been a transfer of control to a stranger to the license and the licensee must adhere to ARM 23.16.117. The department will amend the rule accordingly.

COMMENT #2: The Montana Coin Machine Operators Association (association), through its representative, offered written comment. The association suggested the proposed amendment to ARM 23.16.1802(9) could be improved to clarify the scope of the definition. The association opined the proposed definition of an EPRS (electronic player rewards system) could be read to be overbroad, capturing systems that acquire VGM information for uses other than player rewards. The association requested limiting language.

RESPONSE #2: The department concurs the proposed EPRS definition was intended to include only systems that acquire information for authorized player rewards purposes. The department will amend the proposed definition as suggested by the Montana Coin Machine Operators Association.

COMMENT #3: A major VGM manufacturer submitted a comment regarding ARM 23.16.1904(4), recommending the department substitute the proposed 24-hour malfunction reporting period for a more indefinite reporting period such as "immediately." Alternatively, the commenter suggested a 48-hour reporting period to allow time in which to prepare a malfunction notification which is more in keeping with industry response standards.

RESPONSE #3: The department's aim in the rule amendment was to add manufacturers to those required to report suspected or confirmed VGM malfunctions. To protect the gambling public and gambling operators, the department must learn of malfunctions as soon as is practicable. To ensure prompt reporting, the draft rule established a 24-hour reporting period for manufacturers which is measurable and avoids concerns of vagueness from an indefinite period such as "immediately." However, it is not the department's intent to impose an unreasonable time deadline on manufacturers. To balance the public's and

gambling operators' need for a rapid response against manufacturers' need for sufficient time to research a suspected malfunction, the department will amend the proposed rule to begin the 24-hour reporting period from the time a manufacturer "confirms" a malfunction through a prompt investigation.

COMMENT #4: The Montana Coin Machine Operators Association, through its representative, offered written comment. The association suggested the proposed amendment to ARM 23.16.1918 could be improved to clarify the scope of testing contemplated by the rule. The association observed HB 197 Section 1(9) provides, "If a player rewards system communicates with a video gambling machine, the department shall only test and approve the hardware interface and software interface to ensure that the player rewards system does not affect the play of the video gambling machine." The Association concluded the proposed language of ARM 23.16.1918(1)(b) could be read to allow GCD testing of updates on electronic player rewards systems which are unable to affect the play of a VGM.

COMMENT #5: Similar to Comment #4, the Gaming Industry Association, through its representative, offered oral comments at the public hearing and follow-up written comments concerning the proposed amendment to ARM 23.16.1918. As with Comment #4, the Gaming Industry Association suggested the rule is overbroad and could require GCD testing of EPRS that do not interface with a VGM's software or hardware. The Gaming Industry Association's proposed solution was to add clarifying and limiting language to require testing only if an EPRS interfaces with a VGM.

RESPONSES #4 and #5: The department concurs the legislation, HB 197, disallows EPRS testing except where an EPRS may interface with VGM software or hardware. Though the statute controls, these industry groups remain concerned and suggest the rule could be improved with specificity. The department will insert new language expressly limiting EPRS testing fees to systems interfacing with a VGM.

/s/ Derek Oestreicher

Derek Oestreicher  
Rule Reviewer

/s/ Austin Knudsen

Austin Knudsen  
Attorney General  
Department of Justice

Certified to the Secretary of State January 4, 2022.

BEFORE THE UNEMPLOYMENT INSURANCE APPEALS BOARD  
DEPARTMENT OF LABOR AND INDUSTRY  
STATE OF MONTANA

In the matter of the amendment of ) NOTICE OF AMENDMENT AND  
ARM 24.7.303, 24.7.304, 24.7.305, ) REPEAL  
24.7.306, 24.7.308, 24.7.312, and the )  
repeal of ARM 24.7.201, 24.7.301, )  
24.7.309, 24.7.311, 24.7.313, )  
24.7.315, 24.7.316, and 24.7.320 )  
pertaining to the Unemployment )  
Insurance Appeals Board )

TO: All Concerned Persons

1. On November 19, 2021, the Unemployment Insurance Appeals Board (board) published MAR Notice No. 24-7-387 pertaining to the public hearing on the proposed amendment and repeal of the above-stated rules at page 1611 of the 2021 Montana Administrative Register, Issue Number 22.

2. The Department of Labor and Industry (department) held a public hearing on December 21, 2021, over the Zoom videoconference and telephonic platform at which no members of the public commented. Written comments were received during the public comment period.

3. The board has thoroughly considered the comments made. A summary of the comments and the board responses are as follows:

COMMENT 1: A commenter questioned whether amendments to ARM 24.7.305(3) and (4) would permit a third party administrator for unemployment insurance to appear before the board.

RESPONSE 1: The comment is well-taken. Amendment to the proposal is set forth below.

4. The board has amended ARM 24.7.303, 24.7.304, 24.7.306, 24.7.308, and 24.7.312 as proposed.

5. The board has repealed ARM 24.7.201, 24.7.301, 24.7.309, 24.7.311, 24.7.313, 24.7.315, 24.7.316, and 24.7.320 as proposed.

6. The board has amended ARM 24.7.305 with the following changes, stricken matter interlined, new matter underlined:

24.7.305 BOARD REVIEW PROCEDURE (1) and (2) remain as proposed.  
(3) An interested party to an appeal before the board may appear at any proceeding held in such appeal, either on the party's own behalf, by an attorney at



law, or through an authorized lay representative. Lay representatives may not be paid for the representation unless they are employed by the claimant's labor union, ~~or~~ are an employee of the employer or third party administrator for an employer or group of employers receiving regular wages for the representation, or in the interest of justice at the board's sole discretion.

(4) and (5) remain as proposed.

/s/ LAURA FIX

Laura Fix, Chair  
UNEMPLOYMENT INSURANCE APPEALS  
BOARD

/s/ QUINLAN L. O'CONNOR

Quinlan L. O'Connor  
Rule Reviewer

/s/ LAURIE ESAU

Laurie Esau, Commissioner  
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State January 4, 2022.

BEFORE THE BOARD OF DENTISTRY  
DEPARTMENT OF LABOR AND INDUSTRY  
STATE OF MONTANA

In the matter of the amendment of ARM ) NOTICE OF AMENDMENT  
24.138.402 fee schedule, 24.138.504 )  
approved clinical exam criteria for )  
dentists and dental hygienists, and )  
24.138.508 dental hygiene local )  
anesthetic agent certification )

TO: All Concerned Persons

1. On November 5, 2021, the Board of Dentistry (board) published MAR Notice No. 24-138-81 regarding the public hearing on the proposed amendment of the above-stated rules, at page 1472 of the 2021 Montana Administrative Register, Issue No. 21.

2. On November 30, 2021, a public hearing was held on the proposed amendment of the above-stated rules via the videoconference and telephonic platform. Comments were received by the December 3, 2021, deadline.

3. The board has thoroughly considered the comments received. A summary of the comments and the board responses are as follows:

COMMENT 1: Several commenters supported a fee reduction, but suggested the board reduce hygienists' and dentists' renewal fees by either the same percentage or switch the percentage reductions between license type.

RESPONSE 1: Following consideration of all comments and due to concerns raised by the commenters, the board is not proceeding with the proposed changes to ARM 24.138.402. The board will conduct further discussions to address the issues raised.

4. The board has amended ARM 24.138.504 and 24.138.508 as proposed.

5. The board has not amended ARM 24.138.402.

BOARD OF DENTISTRY  
LESLIE HAYES, DDS  
PRESIDENT

/s/ DARCEE L. MOE  
Darcee L. Moe  
Rule Reviewer

/s/ LAURIE ESAU  
Laurie Esau, Commissioner  
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State January 4, 2022.

BEFORE THE DEPARTMENT OF LABOR AND INDUSTRY  
STATE OF MONTANA

In the matter of the amendment of	)	NOTICE OF AMENDMENT AND
ARM 24.142.402 fee schedule,	)	REPEAL
24.142.2103 continuing education	)	
credits required, and the repeal of	)	
24.142.2102 continuing education	)	
sponsors and courses, all pertaining to	)	
the Elevator Licensing Program	)	

TO: All Concerned Persons

1. On September 10, 2021, the Department of Labor and Industry (department) published MAR Notice No. 24-142-3 regarding the public hearing on the proposed amendment and repeal of the above-stated rules, at page 1117 of the 2021 Montana Administrative Register, Issue No. 17.

2. On October 14, 2021, a public hearing was held on the proposed amendment and repeal of the above-stated rules via the videoconference and telephonic platform. Comments were received by the October 14, 2021, deadline.

3. The department has thoroughly considered the comments received. A summary of the comments and the department responses are as follows:

COMMENT 1: Three commenters opposed the repeal of ARM 24.142.2102, believing that it will diminish the quality of the continuing education (CE) that elevator operators elect to take and that elevator operators will not bother to get the required CE at all.

RESPONSE 1: Repealing ARM 24.142.2102 will not alter or remove the eight-hour annual CE requirement for elevator operators. The department is amending ARM 24.142.2103 to clarify that acceptable CE must be related to installing, altering, repairing, or testing elevators, escalators, and dumbwaiters, or other equipment subject to the provisions of 50-60-704, MCA. Elevator operators are subject to department CE audits, and when operators fail to obtain CE, or take CE that is not relevant, the audit process will discover the noncompliance. The department is repealing ARM 24.142.2102 as proposed.

COMMENT 2: One commenter supported the change, but questioned how the department will monitor elevator operators' completed CE. The commenter also asked if eight hours of CE annually is really necessary since elevator industry technology does not change often.

RESPONSE 2: If an elevator operator is selected for random CE audit, the audit staff will request proof of CE taken and evaluate the submission for compliance with the rules. Because the department did not propose any changes to the required CE

amount, the question is outside of the scope of the current project. The department may consider the suggestion in future rulemaking.

4. The department has amended ARM 24.142.402 and 24.142.2103 and repealed ARM 24.142.2102 exactly as proposed.

/s/ DARCEE L. MOE  
Darcee L. Moe  
Rule Reviewer

/s/ LAURIE ESAU  
Laurie Esau, Commissioner  
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State January 4, 2022.

BEFORE THE DEPARTMENT OF PUBLIC  
HEALTH AND HUMAN SERVICES  
OF THE STATE OF MONTANA

In the matter of the amendment of ) NOTICE OF AMENDMENT  
ARM 37.5.119, 37.27.106, )  
37.106.101, 37.106.106, 37.106.107, )  
37.106.113, 37.106.126, 37.106.133, )  
37.106.134, 37.106.137, 37.106.138, )  
37.106.139, and 37.106.1401 )  
pertaining to certificate of need )

TO: All Concerned Persons

1. On November 19, 2021, the Department of Public Health and Human Services published MAR Notice No. 37-954 pertaining to the public hearing on the proposed amendment of the above-stated rules at page 1619 of the 2021 Montana Administrative Register, Issue Number 22.

2. The department has amended the above-stated rules as proposed.

3. No comments or testimony were received.

4. The department intends to apply these rule amendments retroactively to October 1, 2021. A retroactive application of the proposed rule amendments does not result in a negative impact to any affected party.

/s/ Heidi Sanders  
Heidi Sanders  
Rule Reviewer

/s/ Adam Meier  
Adam Meier, Director  
Public Health and Human Services

Certified to the Secretary of State January 4, 2022.

BEFORE THE DEPARTMENT OF PUBLIC HEALTH  
AND HUMAN SERVICES  
OF THE STATE OF MONTANA

In the matter of the adoption of New ) NOTICE OF ADOPTION AND  
Rules I and II and the amendment of ) AMENDMENT  
ARM 37.107.301, 37.107.302, )  
37.107.303, 37.107.307, 37.107.309, )  
37.107.311, 37.107.313, 37.107.315, )  
and 37.107.316 pertaining to )  
marijuana sampling protocols )

TO: All Concerned Persons

1. On November 19, 2021, the Department of Public Health and Human Services published MAR Notice No. 37-967 pertaining to the public hearing on the proposed adoption and amendment of the above-stated rules at page 1629 of the 2021 Montana Administrative Register, Issue Number 22.

2. The department has adopted the following rule as proposed: New Rule II (37.107.304).

3. The department has amended the following rules as proposed: ARM 37.107.311 and 37.107.313.

4. The department has adopted the following rule as proposed, but with the following changes from the original proposal, new matter underlined, deleted matter interlined:

NEW RULE I (37.107.310) QUALITY ASSURANCE SAMPLING PROTOCOL

(1) and (2) remain as proposed.

(3) Testing laboratories shall create a sampling plan ~~prior to~~ for each sampling event that details at a minimum:

(a) and (b) remain as proposed.

~~(c) the estimated route driven to the site(s) and any detours taken;~~

~~(d) (c) the testing laboratory sampler's license badge ID number;~~

(e) and (f) remain as proposed but are renumbered (d) and (e).

(4) through (7) remain as proposed.

(8) At least 50% of the laboratory test sample must be homogenized prior to its use for the appropriate analysis.

~~(9) Sample increments and/or laboratory test samples from different test batches must not be combined, batched, or composited under any circumstance or at any time. Each test batch requires one laboratory test sample and one complete quality assurance compliance test.~~

(10) remains as proposed but is renumbered (9).

(11) (10) A licensee shall only order tests for marijuana items that the licensee has grown, produced, ~~or processed,~~ or legally purchased from another licensee.

(12) through (15) remain as proposed but are renumbered (11) through (14).

AUTH: 16-12-202, 16-12-209, MCA

IMP: 16-12-202, 16-12-209, MCA

5. The department has amended the following rules as proposed, but with the following changes from the original proposal, new matter underlined, deleted matter interlined:

#### 37.107.301 TESTING LABORATORY ENDORSEMENT REQUIREMENTS

(1) remains as proposed.

(2) An applicant must provide, to the department's state laboratory, documentation to support fulfillment of these requirements, which includes the following:

(a) certificates of insurance and bonding in accordance with ~~[MAR Notice No. 42-1033]~~ ARM 42.39.417;

(b) through (e) remain as proposed.

(f) quality assurance plan manual;

(g) through (5) remain as proposed.

(6) An applicant that meets all of the requirements under the Montana Marijuana Regulation and Taxation Act (Title 16, chapter 12, MCA) and this subchapter and that is actively seeking ISO/IEC 17025:2017 accreditation may be approved for endorsement if written evidence of pending ISO accreditation and an inspection from the state laboratory indicate that accreditation will be achieved within 12 months from the date of endorsement.

(6) through (8) remain as proposed but are renumbered (7) through (9).

AUTH: 16-12-202, 16-12-209, MCA

IMP: 16-12-202, 16-12-209, MCA

#### 37.107.302 TESTING LABORATORY GENERAL REQUIREMENTS

(1) remains as proposed.

(2) The scientific director must ensure that:

(a) and (b) remain as proposed.

(c) the testing laboratory maintains quality practices in accordance with their quality assurance plan manual;

(d) through (g) remain as proposed.

(h) test method validations have been performed initially and upon test method changes to determine the minimum following requirements as appropriate;

(i) through (10) remain as proposed.

AUTH: 16-12-202, 16-12-209, MCA

IMP: 16-12-202, 16-12-209, MCA

37.107.303 DEFINITIONS As used in this subchapter, the following definitions apply:

(1) through (14) remain as proposed.

~~(15) "Good laboratory practice (GLP)" means a system of management controls for testing laboratories to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of analyses performed by the testing laboratory.~~

~~(16)~~ (15) "Harvest lot" means a specifically identified quantity of marijuana that is cultivated utilizing the same growing practices, harvested within a 72-hour period at the same location, and cured under uniform conditions, and uniform in strain. A harvest lot may contain multiple strains.

(17) through (21) remain as proposed but are renumbered (16) through (20).

~~(22)~~ (21) "Laboratory control sample (LCS)" means a quality control sample that includes each of the target analytes at the mid-range of the calibration spiked into an analyte free matching matrix or a matrix that is as closely representative of the matrix being analyzed as possible, in order to evaluate the efficiency of the preparatory/extraction process. The LCS is prepared in the same manner as the rest of the laboratory test samples in the analytical batch. An LCS is required for contaminant testing only.

(23) through (50) remain as proposed but are renumbered (22) through (49).

~~(50)~~ "Total potential psychoactive THC" has the meaning provided for under ARM 42.39.102.

~~(51) "Total CBD" means the sum of CBD and CBDa calculated using the following equation:~~

~~(a) Total CBD mg/g=(CBDa mg/g x 0.877)+CBD mg/g~~

~~(52)~~ (51) "Total THC" means the sum of THC and THCa calculated using the following equation:

~~(a) Total THC mg/g=(THCa mg/g x 0.877)+THC mg/g.~~

(53) remains as proposed but is renumbered (52).

AUTH: 16-12-202, 16-12-209, MCA

IMP: 16-12-202, 16-12-209, MCA

37.107.307 TESTING LABORATORY QUALITY ASSURANCE PROGRAM

(1) The testing laboratory shall develop and implement a quality assurance program to assure the reliability and validity of the analytical data produced by the testing laboratory. The quality assurance program shall, at a minimum, include a written quality ~~assurance plan or~~ manual that addresses the following:

(a) remains as proposed.

(b) testing laboratory organization and employee training and responsibilities, ~~including good laboratory practice (GLP);~~

(c) through (l) remain as proposed.

(2) The scientific director shall annually review, amend if necessary, and approve the quality ~~assurance program and plan~~ manual both when ~~they are~~ it is created and when there is a change in methods, laboratory equipment, or the scientific director.

(3) All testing laboratory personnel shall review the quality ~~assurance plan~~ manual upon revision or at least annually.



AUTH: 16-12-202, 16-12-209, MCA

IMP: 16-12-202, 16-12-209, MCA

37.107.309 TESTING LABORATORY QUALITY CONTROL (1) The testing laboratory shall use quality control samples and adhere to ~~good laboratory practices (GLP)~~ ISO 17025:2017 in the performance of all quality assurance testing according to the following specifications:

(a) through (4) remain as proposed.

(5) If any quality control sample result is outside the testing laboratory's specified acceptance criteria listed in the testing laboratory's quality ~~assurance plan~~ manual, specific method SOP, or product instructions for use, the testing laboratory shall determine the cause and take corrective action steps to remedy the problem until the result is within the specified acceptance criteria.

(6) and (7) remain as proposed.

AUTH: 16-12-202, 16-12-209, MCA

IMP: 16-12-202, 16-12-209, MCA

37.107.315 TESTING LABORATORY FAILED LABORATORY TEST SAMPLES (1) remains as proposed.

(2) When a testing laboratory performs quality assurance testing, the testing laboratory must verify that the following quality control criteria are within acceptable limits based upon the testing laboratory's method specific standard operating procedures, the testing laboratory quality ~~assurance plan~~ manual, and the manufacturer's instructions for use, if applicable:

(a) through (3) remain as proposed.

(4) A licensee may request that the testing laboratory resample the failed batch or lot for repeat testing within seven calendar days of receiving notice from the testing laboratory of any failed testing and resampled analyses must be completed by the testing laboratory within ~~30~~ 10 days of receiving the request from the licensee.

(5) through (7) remain as proposed.

(8) If the quality control criteria for initial quality assurance testing are not within acceptable limits, then the results of all laboratory test samples within an analytical batch are considered invalid (failed run) and the entire run must be repeated with new quality controls and not reported to the licensee.

(9) The testing laboratory should document and investigate failed runs, as part of the testing laboratory's quality ~~assurance plan~~ manual, to determine the root cause of the failure and whether corrective and preventative action measures are warranted.

(10) through (13) remain as proposed.

(14) With the exception of moisture analysis or residual solvent screening, a ~~remediated~~ laboratory test sample from a ~~failed~~ remediated harvest lot, process lot, or test batch that fails quality assurance testing cannot be remediated again and the harvest lot, process lot, or test batch must be destroyed. Harvest lots, process lots, or test batches that fail initial quality assurance testing for moisture analysis or

residual solvent screening may be remediated and retested a maximum of two times. ~~Test batches that fail pesticide analysis cannot be remediated and shall be destroyed.~~

(15) The testing laboratory must document all sampling, resampling, testing, retesting, ~~remediation attempts~~, and results under this subchapter.

AUTH: 16-12-202, 16-12-209, MCA

IMP: 16-12-202, 16-12-209, MCA

37.107.316 TESTING LABORATORY QUALITY ASSURANCE TESTING REQUIREMENTS (1) and (2) remain as proposed.

(3) The cannabinoid profile/potency for each sample must include:

(a) and (b) remain as proposed.

(c) Total potential psychoactive THC for marijuana items that require the application of heat for administration/consumption only;

(d) CBDA; and

(e) CBD; ~~and~~

(f) ~~Total CBD.~~

(4) and (5) remain as proposed.

(6) The laboratory test sample and related lot or test batch fail quality assurance testing for microbiological screening if the results are greater than the following action levels:

(a) Salmonella species: non-detectable in 1.0 gram of material;

(b) Shiga-toxin producing Escherichia Coli coli (STEC): non-detectable in 1.0 gram of material; and

(c) remains as proposed.

(7) Microbiological testing using molecular methods must include an enrichment step that follows the protocol provided by the manufacturer, molecular method used, or product instructions for use. Decreasing the enrichment time outside of the range provided above is strictly prohibited.

(8) through (12) remain as proposed.

AUTH: 16-12-202, 16-12-209, MCA

IMP: 16-12-202, 16-12-209, MCA

6. The department has thoroughly considered the comments and testimony received. A summary of the comments received, and the department's responses are as follows:

COMMENT #1: Numerous commenters expressed opposition to increasing the test batch size from 5 to 10 pounds and revising the definition of "harvest lot" to require a uniform strain rather than multiple strains. The primary reasons cited in opposition to these changes included the short implementation timeline, added expense of testing, changes being too burdensome to providers, disruption to the supply chain, creation of a bottleneck of strains, lack of necessity, and scaling up too fast.

RESPONSE #1: The department partially agrees with the commenters and has revised the *Quality Assurance Sampling Protocol for Usable Marijuana, Marijuana Concentrates and Extracts, and Marijuana Infused Products* (SOP-001) to maintain a 5-pound test batch. The definition of "harvest lot" has also been revised to remain multiple in strain at this time. The department intends to initiate a separate rulemaking in the near future to address strain compositing in harvest lots. See Response #2 for more information pertaining to strain compositing in test batches and the reason for addressing the issue through future rulemaking.

COMMENT #2: Multiple commenters expressed support for the increase in test batch size from 5 to 10 pounds and the change in the definition of "harvest lot" from being multiple in strain to uniform in strain. The primary reasons cited in support of these changes included that single strain test batches will provide safer and better-quality products, the changes reflect more valid scientific practices, and larger providers will appreciate the increase to 10-pound test batches. It was suggested that allowing a certain number of strains per harvest lot instead of moving directly to a single strain system could be a feasible option. Recommendations on the number of strains allowed ranged from 3 to 10.

RESPONSE #2: See Response #1 concerning the department's decision on test batch size. The department agrees that single strain harvest lots will increase product safety. Multi-strain harvest lots have become a serious problem. The compositing of a large number of strains into one test batch effectively dilutes the presence of any contaminant that may exist in any of the strains within the laboratory test sample. When too many strains are composited into one laboratory test sample, the detection of contaminants becomes impossible even with the most sophisticated instrumentation. The adage "dilution is the solution to pollution" is effectively what is occurring here. The practice, if unchecked, could provide Montana customers with misleading test results. The practice of compositing 20, 30, or even more strains into one 5-pound test batch is prevalent in the industry. This practice has the potential to negatively impact the industry if an illness related to strain compositing occurred or a product recall were issued.

The department agrees that determining a minimum number of strains that can be allowed into one harvest lot may be a feasible option. The number of strains must be attainable and scientifically supported by all licensed testing laboratories' methods. However, the department believes additional stakeholder input is needed before it can adopt such a requirement. The potential change represents a significant departure from what is proposed in the rules. Therefore, the department believes the best course of action is to address the issue through separate rulemaking in the near future.

COMMENT #3: Numerous commenters expressed opposition to delayed implementation of new testing requirements. The commenters indicated the new testing requirements should have been anticipated and that any delay in implementation will adversely impact access to safe and legal marijuana. Some of these commenters also suggested that existing rules accommodate the original

implementation date, ISO accreditation is not strictly necessary, and administrative and reporting conflicts will arise.

RESPONSE #3: The department disagrees. These proposed rules did not become publicly available and known to stakeholders until after filing with the Secretary of State on November 9, 2021. The new testing requirements could not have been reasonably anticipated prior to that time. The department has also received numerous comments in support of delaying implementation of the new testing requirements, which are summarized in Comment #4. Having carefully considered the comments supporting and the comments opposing delayed implementation, the department has determined the best course of action to ensure orderly implementation of the rules is to partially delay implementation of the new testing requirements. Specifically, the department is delaying implementation of new requirements relating to STEC and speciated aspergillus testing proposed under ARM 37.107.316(6)(b), (6)(c), and (7). The proposed rules have been revised to make these testing requirements effective March 14, 2022, a period of three months from the date of adoption of the remainder of the rules. The delayed implementation provides a reasonable time period for laboratories to take measures necessary to meet the new testing requirements. During this time period, culturable mold and E. coli testing requirements in existence under current rule remain in effect. The department believes this brief period of delayed implementation will not impact access to safe and legal marijuana products because laboratories will be subject to all other testing requirements contained in the proposed rules as well as SOP-001.

COMMENT #4: Numerous commenters expressed support for delaying implementation of the new testing requirements. These commenters suggested adequate time is necessary for laboratories who are not currently using PCR. Additionally, the commenters suggested additional time is necessary to procure and set up instrumentation, validate methodology, adequately train employees, write new SOPs, pass proficiency testing, and begin adding new methods to laboratory ISO scopes of accreditation. Recommended timelines for implementation ranged from 3 to 12 months.

RESPONSE #4: The department partially agrees with these commenters. The partial delay in implementation described under the response to Comment #3 balances the need for ensuring new testing requirements are not rushed and that quality method validation is achieved prior to testing while also ensuring timely implementation of House Bill (HB) 701.

COMMENT #5: Several commenters suggested an estimated route driven is unnecessary for the sampling plan.

RESPONSE #5: The department agrees, and has revised New Rule I accordingly.

COMMENT #6: Several commenters expressed concerns about the mandatory enrichment step for molecular methods under ARM 37.107.316(7) and requested

that specific requirements, reagents, and incubation times be listed in rule for clarification.

RESPONSE #6: The department partially agrees with the stated concerns. Clarification is needed, but the proposed changes offered by the commenters are too specific. The department has revised the rule for clarity. However, due to the continuing advancement of instrumental analysis, particularly in the molecular analysis of marijuana, the revisions do not provide specific instruction on reagents, methods, or incubation times.

COMMENT #7: Several commenters raised concerns about the difficulty to open and remove marijuana concentrates from vapor cartridges and suggested allowing sample collection prior to packaging into cartridges instead of directly from cartridges.

RESPONSE #7: The department understands that retrieving marijuana extract from cartridges can pose unique challenges. However, the department disagrees that these challenges outweigh the health and safety benefits of testing the concentrate directly from the cartridge. Testing the concentrate from the cartridge will ensure a truly safe vapor product for Montana customers.

COMMENT #8: Numerous comments were received concerning proficiency testing. Issues raised by these commenters included ISO/IEC 17043 requirements, inter/intra laboratory studies, random compliance checks, frequency of proficiency testing, rules which allow the state to determine which proficiency tests to conduct, and discrepancies between laboratory standard operating procedures and proficiency testing provider instructions.

RESPONSE #8: The changes suggested by the commenters represent a significant departure from what is proposed in the rules. The department will consider the concerns raised by the commenters as part of future rulemaking where additional public input can be considered.

COMMENT #9: Several commenters suggested removing language in ARM 37.107.315(3), (8), and (9) on the basis that ARM 37.107.315(5) and (6) adequately address failed laboratory test samples and quality control samples.

RESPONSE #9: The department disagrees. Each of the rules has a purpose and clearly defines different scenarios in which laboratory test samples, quality control samples, resamples, data, and corrective/preventative action plans shall be handled.

COMMENT #10: Several commenters suggested increasing the percent moisture action level under ARM 37.107.316 from 12.0% to 14.0%.

RESPONSE #10: The department will consider this suggestion as part of future rulemaking where additional public input can be considered.

COMMENT #11: Several comments were received that section 4.1.5 of SOP-001 should allow sampling scales capable of 0.1g measurements rather than 0.01g measurements because 0.01g measurements are exorbitant.

RESPONSE #11: The department agrees, and has revised SOP-001 accordingly.

COMMENT #12: Several commenters suggested that remediation language under ARM 37.107.315(15) be removed because laboratories do not have control over licensee strategy, action to remediate samples, or failed sample destruction.

RESPONSE #12: The department agrees with the commenters, and has revised the rule accordingly.

COMMENT #13: A commenter stated laboratories do not have access to the mass recorded by the seed-to-sale tracking system in order to confirm the entire test batch is available and that the test batch mass is currently provided verbally by the licensee.

RESPONSE #13: The department understands that the mass of the test batch is provided to the sampler by the licensee and the laboratories do not have access to this value in the seed-to-sale system. The department has revised SOP-001 accordingly to adjust for this step, given the laboratories' lack of access to such information.

COMMENT #14: A commenter requested clarification on final form testing as well as when and what items require testing. The commenter provided extensive suggested rule text to be made part of the rules.

RESPONSE #14: The changes suggested by the commenter represent a significant departure from what is proposed in the rules. The department will consider the concerns raised by the commenter as part of future rulemaking where additional public input can be considered.

COMMENT #15: A commenter suggested a start and end time under New Rule I is unnecessary for the sampling plan.

RESPONSE #15: The department partially disagrees. A start and end time provides a timeline to track the sampling event for that day. The start and end time does not need to be known ahead of time. It can simply be entered into the laboratory sampling plan when the sampler leaves and returns from the day(s) of sampling. The department has revised the rule for clarity to indicate the start and end times do not need to be recorded prior to the sampling

COMMENT #16: A commenter requested "total THC" be removed from ARM 37.107.316(3)(c) and "total CBD" removed from ARM 37.107.316(3)(f) to conform to Department of Revenue (DOR) labeling rules that include "total potential

psychoactive THC." It was also suggested to include "total psychoactive CBD" in ARM 37.107.316(3)(f).

RESPONSE #16: The department partially agrees. Amending these rules to better conform to DOR labeling rules is necessary to ensure consistency and avoid confusion. The department has revised the rule to include "total potential psychoactive THC" for products that require heat for administration/consumption only. The department has also revised the rule to remove reporting "total CBD" and to remove the definition of "total CBD" since the term is no longer used within the rules. The department disagrees that adding "total psychoactive CBD" conforms to DOR labeling rules; this term does not exist in the DOR rules nor is "total CBD" considered psychoactive.

COMMENT #17: A commenter suggested clarifying when to calculate a method detection limit (MDL) in ARM 37.107.302(2)(h) and stated some types of contaminate analysis do not facilitate calculation of this value.

RESPONSE #17: The department agrees, and has clarified in rule when an MDL shall be calculated.

COMMENT #18: A commenter stated that ARM 37.107.315(2) and ARM 37.107.309 are redundant.

RESPONSE #18: The department disagrees with this comment. The quality control sample types are stated in both rules. However, ARM 37.107.309 also informs readers on how to address failed samples and quality controls; ARM 37.107.315(2) does not. Additionally, standard curves, coefficient of determination, positive and negative controls, and cycle thresholds are addressed in ARM 37.107.315(2), but not addressed in ARM 37.107.309.

COMMENT #19: A commenter requests removal of language under ARM 37.107.315(14) prohibiting remediation of test batches that fail pesticide analysis. The commenter states that certain pesticides degrade over time and simply require more time between harvest and analysis to degrade to safe levels that meet testing standards.

RESPONSE #19: The department agrees, and has revised the rule accordingly.

COMMENT #20: A commenter stated that the pesticide Spiromesifen was included in previous versions of the department's administrative rules and made part of action level tables. The commenter suggests including Spiromesifen in the current pesticide table under ARM 37.107.316.

RESPONSE #20: Spiromesifen was included in action level tables in a past version of the department's rules, but was removed in a prior rule amendment and is not part of current rule. The addition of the pesticide at this time is not advisable as it could have unintended consequences. Some laboratories may not currently have method

validations that include this contaminant. The department will consider the issue raised by the commenter as part of future rulemaking that considers an adequate timeline for laboratories to come into compliance with analyzing this specific pesticide.

COMMENT #21: A commenter suggested tables 2.0, 3.0, 4.0, and 5.0 of SOP-001 do not provide adequate sample volume for analysis for the lowest tiers of each table.

RESPONSE #21: The department disagrees with this comment. Every laboratory has different validated methods and some laboratories may be able to perform sample analysis using smaller sample volumes. The required sample volume may also change over time as new advancements in instrumentation and preparatory methods emerge. New Rule (l)(6) states: "[t]he testing laboratory sampler shall collect a laboratory test sample that is random and representative of the test batch, meets the standards of the state laboratory's 'Quality Assurance Sampling Protocol for Usable Marijuana, Marijuana Concentrates and Extracts, and Marijuana Infused Products' SOP-001, *and is sufficient to complete all required quality assurance testing including quality control samples and re-runs.*" (Emphasis added). This indicates that if the sample mass provided in the tables is insufficient for a laboratory to analyze then the laboratory sampler is permitted to collect more sample mass. Please also see the response to Comment #65.

COMMENT #22: A commenter requested the random designation of heavy metal testing be removed and officially included in quality assurance compliance testing as it increases the safety of marijuana products and multiple labs have the instrumentation available.

RESPONSE #22: The department disagrees that multiple labs are currently capable of immediately implementing heavy metal testing. The department plans to address this issue in future rulemaking where the fiscal impact of such testing and an appropriate implementation period can be considered.

COMMENT #23: A commenter suggested adding language to ARM 37.107.309 concerning LOD, LOQ, and propagated experimental error. It was suggested this data should be included in the certificate of analysis.

RESPONSE #23: The department will consider the suggested changes as part of future rulemaking where additional public input can be considered.

COMMENT #24: A commenter suggested adding new rules concerning what items should be required on the certificates of analysis.

RESPONSE #24: Implementation of the commenter's suggested changes would require new rules to address required information for a certificate of analysis. The commenter's suggested changes will be taken into consideration as part of future rulemaking.



COMMENT #25: A commenter requested clarification of ARM 37.107.302(4) concerning how 75% of the testing capability is determined and suggested the rule be revised to reference 75% of quality assurance testing panels.

RESPONSE #25: The department will consider the suggested change as part of future rulemaking where additional public input can be considered.

COMMENT #26: A commenter suggested the 30-day time period for resampling under ARM 37.107.315(4) is too long and should be changed to five days.

RESPONSE #26: The department agrees that the 30-day time period is unnecessarily long, but disagrees that five days affords enough time for resampling. The department believes 10 days represents a reasonable time period to complete resampling and has revised the rule accordingly.

COMMENT #27: A commenter suggested that ARM 37.107.315(8) is unclear and redundant to ARM 37.107.309.

RESPONSE #27: The department partially agrees with the comment, and has revised ARM 37.107.315 for clarity. If quality control samples fail on the initial run, the results of the associated laboratory test samples shall not be reported to the licensee. Those same initial results shall only be reported into the laboratory information management system and seed-to-sale tracking system. The department disagrees the rules are redundant because ARM 37.107.309 separately addresses corrective action steps.

COMMENT #28: A commenter suggested revising ARM 37.107.316 by increasing the percent seeds action level for filth and foreign matter analysis from 2.0% to 5.0%.

RESPONSE #28: The commenter's suggested change represents a significant departure from what is proposed in the rules. The department will consider the suggestion as part of future rulemaking where the public has an opportunity to comment on the suggested change.

COMMENT #29: A commenter remarked on the laboratory moratorium discussions that took place before the Economic Affairs Interim Committee and expressed opposition to a moratorium. The commenter indicated a moratorium is unnecessary, would decrease competition, and could result in an inability to meet testing demand.

RESPONSE #29: The comment is outside the scope of this rulemaking process. The department's proposed rules are unrelated to and do not implicate the issue of a moratorium.

COMMENT #30: A commenter suggested the department inspect laboratories when new contaminate testing methods are implemented.

RESPONSE #30: The department agrees that new methods will require the state laboratory to assess each laboratory to ensure the proper equipment, method validations, proficiency testing, and ISO accreditation are present. The rules as proposed allow for these assessments and inspections to take place.

COMMENT #31: A commenter requested clarification regarding New Rule I(8) specifying that the unhomogenized portion of the laboratory test sample shall not be used for analysis.

RESPONSE #31: Under the rule, a portion of the sample that is unhomogenized must be maintained to complete filth and foreign matter screening. The intent of the rule is for the majority of the testing to be completed using the homogenized portion of the laboratory test sample. The department has revised the rule for clarity.

COMMENT #32: A commenter expressed opposition to the proposed removal of existing rule language under ARM 37.107.301(6) allowing 12 months for new laboratories to attain ISO 17025:2017 accreditation after licensure. The commenter suggested the language should instead be amended to allow testing laboratories who applied for licensure prior to January 1, 2022, a period of six months to attain accreditation.

RESPONSE #32: The department agrees that a reasonable time period is needed to allow testing laboratories to operate while actively working toward completion of the process of obtaining ISO accreditation. Such a time period is necessary to allow for an orderly transition to these new rules and to ensure that the necessary testing capacity exists to meet the anticipated demands of the market as Montana transitions to recreational marijuana. The department disagrees that the time period should be limited in application only to testing laboratories who started the ISO accreditation process prior to January 1, 2022. Such a limitation would effectively create differing requirements for testing laboratories depending upon the date of application. The approach taken by the department in proposing these rules has been to provide for a uniform set of rules that apply equally to current and future testing laboratories. Consistent with this approach, the department is revising the rule to allow endorsement of a testing laboratory that meets all other requirements of rule if written evidence of pending ISO accreditation and the results of an audit indicate that accreditation will be achieved within 12 months from the date of endorsement. A period of 12 months, rather than six months, has been chosen because it is consistent with the time period in the past rule, and the department's experience with implementation of the past rule is that the process of obtaining ISO accreditation can take longer than six months even in cases where a testing laboratory is diligently working toward accreditation.

COMMENT #33: A commenter stated that rules requiring new test methods must be implemented at the same time for all laboratories and new laboratories should not perform different tests on the same products compared to existing laboratories.

RESPONSE #33: The department agrees. The rules as proposed do not allow for laboratories to test for different analytes.

COMMENT #34: A commenter expressed concerns about the transition process from existing law to HB 701 and the department's proposed rules once they take full effect. The commenter indicated that a single set of rules should apply equally to both new testing laboratories and laboratories in existence prior to January 1, 2022. The commenter stated that a delay in implementation of new testing requirements is necessary to achieve this goal.

RESPONSE #34: Please see the response to Comment #3 on delayed implementation of new testing requirements. These proposed rules, and the revisions made in response to comments received, apply both to testing laboratories in existence prior to January 1, 2022, and to future testing labs.

COMMENT #35: A commenter sought clarification on how new laboratory license fees will apply to testing laboratories who started the process of acquiring a laboratory license prior to January 1, 2022.

RESPONSE #35: The comment is outside the scope of this rulemaking process. Under HB 701, rulemaking authority relating to testing laboratory fees rests with the Department of Revenue. 16-12-112, MCA.

COMMENT #36: A commenter requested the department adopt confidentiality rules to protect the proprietary nature of laboratory methods.

RESPONSE #36: The change proposed by the commenter is outside the scope of this rulemaking.

COMMENT #37: A commenter suggested revising ARM 37.107.316(6)(a) to reference "*Salmonella* species" to indicate any type of salmonella rather than just referencing "*Salmonella*."

RESPONSE #37: The department agrees with the comment, and has revised the rule accordingly.

COMMENT #38: A commenter suggested making the reference to "Coli" under ARM 37.107.316(6)(b) lowercase.

RESPONSE #38: The department agrees, and has revised the rule accordingly.

COMMENT #39: A commenter suggested revising ARM 37.107.316(7) to require use of an enrichment step for any method of microbiological testing.

RESPONSE #39: The commenter's suggested change represents a significant departure from what is proposed in the rules. The department will consider the

suggestion as part of future rulemaking where the public has an opportunity to comment on the suggested change.

COMMENT #40: A commenter suggested reorganizing New Rule I(4) through (15) to reflect the order of operations for which these provisions ordinarily occur.

RESPONSE #40: The department does not believe the suggested change is needed. Rearrangement of the order of these sections of the rule would not increase clarity or understanding of the rule.

COMMENT #41: A commenter suggested clarifying New Rule I(11) to better accommodate the horizontal market.

RESPONSE #41: The department agrees, and has revised the rule to include product that has been purchased from another licensee.

COMMENT #42: A commenter suggested allowing a certain amount of time to field test the SOP-001 sampling protocol before it takes effect so laboratories could provide additional comment and SOP-001 could be further revised.

RESPONSE #42: Implementation of a sampling protocol is statutorily required by HB 701 and cannot be delayed. Revisions to SOP-001 must occur through the rulemaking process. If testing laboratories come across major issues or concerns with respect to implementing or operationalizing the protocol, they should contact the department; rulemaking can be initiated if warranted.

COMMENT #43: A commenter suggested adding a rule to clarify laboratory inspections shall be performed solely by approved members of the Public Health Laboratory of the Montana Department of Public Health and Human Services.

RESPONSE #43: The department disagrees. Amending the rules to make the department the only entity allowed to conduct inspections of testing laboratories would conflict with DOR's authority to conduct inspections under the Montana Marijuana Regulation and Taxation Act. See, e.g., 16-12-210, MCA.

COMMENT #44: A commenter requested standardization of use of the term "quality assurance plan" to match that of ISO 17025:2017, which uses "quality management system" or "quality manual."

RESPONSE #44: The department agrees with the comment, and has revised the rules by removing references to "quality assurance plan" and replacing it with "quality manual."

COMMENT #45: Several commenters expressed the opinion that portions of the proposed rules are redundant and duplicative of the ISO 17025:2017 accreditation standards and should be removed. In particular, the commenters questioned the need for ARM 37.107.302(2)(d) though (n), (6), (7), and 37.107.307.

RESPONSE #45: The department disagrees with the comments. Removing these rules would drastically reduce the ability of the department to adequately conduct thorough and meaningful inspections and to provide adequate oversight of testing laboratories.

COMMENT #46: A commenter suggested that the definition "good laboratory practice" and all references to it be removed from rule and replaced with ISO 17025:2017.

RESPONSE #46: The department agrees with the comment, and has revised the rules accordingly.

COMMENT #47: A commenter suggested the definition of "laboratory control sample" under ARM 37.107.303 be revised to exclude potency testing. The commenter stated reference standards for cannabinoids are expensive and the concentration of those cannabinoids in reference standards is heavily regulated by the Drug Enforcement Administration making this quality control sample for potency testing unnecessarily burdensome.

RESPONSE #47: The department agrees with the comment, and has revised the definition of "laboratory control sample" to include language indicating this quality control sample is for contaminate testing only.

COMMENT #48: A commenter suggested the definition of "method blank" under ARM 37.107.303 be revised to allow for a reagent method blank as finding a clean method blank can be difficult.

RESPONSE #48: The department disagrees. The definition of "method blank" provides adequate flexibility for laboratories to use a closely matched clean matrix from which to prepare a method blank. Laboratories may exercise their reasonable discretion in deciding what is a closely matched matrix. Reagent method blanks can be used at the discretion of laboratories to confirm reagents are clean. However, reagent method blanks do not confirm that the extraction/preparatory method is free of contamination.

COMMENT #49: A commenter suggested further clarifying the definition of "process lot" under ARM 37.107.303 to narrow the classification to just the extraction step.

RESPONSE #49: The department disagrees with the comment, and believes the definition of "process lot" is sufficiently clear as written.

COMMENT #50: A commenter suggested removing units from the equations defining "total THC" and "total CBD" under ARM 37.107.303 to clarify that other units may be used so long as the units for each term remain the same.

RESPONSE #50: The department agrees, and has revised the rule to remove reference to units for "total THC." The definition of "total CBD" has been removed entirely in response to Comment #16.

COMMENT #51: A commenter expressed concern with the time period under ARM 37.107.313(3)(a) for notification of an unsuccessful proficiency result and suggests keeping five business days or increasing the time to 10 business days.

RESPONSE #51: The department disagrees, and believes the proposed time period of three business days is adequate and reasonable. The proposed change also aligns with existing rule language under ARM 37.107.311(8) providing three business days to report to the department.

COMMENT #52: A commenter suggested that test batches should be removed from remediation requirements under ARM 37.107.315(11) because inclusion of test batches implies testing laboratories are responsible for remediation.

RESPONSE #52: The department disagrees that the rule implies testing laboratories are responsible for product remediation. ARM 37.107.315(11) simply states the circumstances under which failed harvest lots, process lots, or test batches may be remediated.

COMMENT #53: A commenter suggested ARM 37.107.315(14) be revised to clarify the intent is for failed harvest lots, process lots, and test batches to be remediated and not the laboratory test sample.

RESPONSE #53: The department agrees and has revised the rule accordingly.

COMMENT #54: A commenter suggested to keep general E. coli testing as STEC narrows the field of testing too much and will eliminate other pathogenic forms of E. coli. The commenter requests that if STEC is to remain in rule that laboratories are provided adequate time to implement the change.

RESPONSE #54: The department disagrees with the comment. STEC narrows testing to include the most common sources of pathogenic E. coli contamination similar to the manner in which culturable mold testing was narrowed to include common pathogenic forms such as aspergillus. Please see the response to Comment #3 regarding delayed implementation of this testing requirement.

COMMENT #55: A commenter suggested the action level for chloroform be updated from 2ppm to 60ppm to match that of Q3C - Tables and List Guidance for Industry maintained by the Food and Drug Administration.

RESPONSE #55: The commenter's suggested change represents a significant departure from what is proposed in the rules. The department will consider the suggestion as part of future rulemaking where the public has an opportunity to comment on the suggested change.

COMMENT #56: A commenter suggested existing rule language under ARM 37.107.316(12)(b) is inadvertently leading to certain marijuana products, such as cannabis butter, being inadequately tested because the products in question are only subject to testing under ARM 37.107.316(12)(e).

RESPONSE #56: The intent of the rules is to ensure all marijuana products undergo testing prior to reaching the end consumer. With respect to the commenter's specific example, the department refers to ARM 37.107.316(12)(f), which indicates marijuana concentrate and extract must pass the required testing set forth in ARM 37.107.316(12)(d).

COMMENT #57: A commenter suggested the calibration weight check requirements under section 4.1.6 of SOP-001 are excessive and multiple weight checks would have to happen at one facility.

RESPONSE #57: The department believes that the commenter has misinterpreted the referenced provision. The language states a balance weight check shall occur at each licensed facility. One weight check, not multiple weight checks, is required at each licensed facility.

COMMENT #58: A commenter suggested that trademark names should be removed from SOP-001.

RESPONSE #58: The department agrees, and has revised SOP-001 accordingly.

COMMENT #59: A commenter noted a spelling error in section 4.1.10 of SOP-001.

RESPONSE #59: The department has corrected the spelling error.

COMMENT #60: A commenter requests that references to hair nets and beard nets be removed from section 4.1.10.1 of SOP-001 as these requirements are more appropriate for other licensee types rather than testing laboratories.

RESPONSE #60: The department agrees, and has revised SOP-001 accordingly.

COMMENT #61: A commenter suggested removing the requirement under section 6.2 of SOP-001 for an internal field audit and indicated ISO 17025:2017 is adequate for addressing laboratory training.

RESPONSE #61: The department disagrees. The requirement is necessary to ensure testing laboratory samplers are consistently trained throughout the state.

COMMENT #62: A commenter suggested SOP-001 will be more time consuming and suggested removing provisions that increase the time needed to collect samples. Specific recommendations were not provided.

RESPONSE #62: The department understands SOP-001 will require additional time for sampling. However, the benefits of SOP-001 in establishing a uniform standard for sampling outweigh the resulting extra time needed to acquire a quality representative sample.

COMMENT #63: A commenter suggested revising the proposed rules to require use of standardized storage containers and packaging for all licensees to make sample collection easier.

RESPONSE #63: This comment is outside the scope of the rulemaking. Rulemaking authority relating to packaging rests with DOR. 16-12-112, MCA.

COMMENT #64: A commenter suggests changing the percent difference in sections 7.1.4.3, 7.2.4.3, 7.3.4.3, and 7.4.4.3 of SOP-001 from  $\pm 10.0\%$  to  $\pm 5.0\%$ .

RESPONSE #64: The department disagrees. This value was established with the intent to provide for a somewhat lenient margin of error in order to allow for a smooth transition toward implementation of SOP-001. The department will re-evaluate this value as SOP-001 is implemented, and can modify it through future rulemaking if warranted.

COMMENT #65: A commenter suggested that 80 increments of flower will require 60 to 70 increments to be very small. The department believes the commenter meant 8 increments will require 6 to 7 increments to be very small. It was recommended that sample increment values be reduced by half and sample size weights be rounded to the nearest whole number.

RESPONSE #65: The rules do not require increments be the same size. The rules allow for more increments to be collected than what is listed in the sampling tables of SOP-001. The department has revised SOP-001 to clarify that additional mass may also be collected to help facilitate this process.

COMMENT #66: A commenter suggested removing the sample mixing requirement for flower in section 7.1.11 of SOP-001 and indicated that mixing will damage trichomes and subsequently change the potency results.

RESPONSE #66: The department disagrees with the comment. Mixing a sample is a necessary part of collecting a representative sample of any matrix. The amount of mixing required will not significantly affect potency results any more than the routine handling of the product for packaging, transport, etc.

COMMENT #67: A commenter suggested moving distillates from section 7.3 to section 7.2 of SOP-001 because they are considered semi-solids. The commenter also recommended including Rick Simpson Oil under section 7.3.

RESPONSE #67: The department agrees, and has revised SOP-001 accordingly. However, please note the list provided in headings of SOP-001 such as sections 7.2



and 7.3 are merely examples and are not complete or exhaustive lists. Exceptions to these headings will exist and it is at the reasonable discretion of the laboratory sampler to properly assign a product to the best sampling procedure.

COMMENT #68: A commenter suggested adding language to section 7.4.8 of SOP-001 to clarify the minimum number of vape cartridges for sampling and noted that not all the extract can be removed from one cartridge.

RESPONSE #68: The department disagrees. New Rule I(6) already specifies that the laboratory test sample collected shall be sufficient to allow for analysis and reruns. It is the responsibility of the laboratory to understand that removal of all extract vape from cartridges is impossible and that collection of additional cartridges may be necessary.

COMMENT #69: A commenter suggested adding a column to Table 5.0 of SOP-001 to clarify the minimum number of servings.

RESPONSE #69: The department believes this change is unnecessary because section 7.5.7 of SOP-001 explicitly states that one serving size is equal to one sample increment.

COMMENT #70: A commenter suggested providing an example of what an acceptable random number generator would be under section 7.6 of SOP-001.

RESPONSE #70: The department agrees, and has revised SOP-001 to include examples.

COMMENT #71: A commenter suggested revising section 7.6.7 of SOP-001 to allow custody seals on bulk bags or individual laboratory test samples, to save time and resources.

RESPONSE #71: The department agrees, and has revised SOP-001 accordingly.

COMMENT #72: A commenter suggested removing time requirements from section 7.6.8.6 and removing sections 7.6.8.8 and 7.6.8.9 from SOP-001. The commenter indicated these requirements are excessive.

RESPONSE #72: The department agrees the time requirement under section 7.6.8.6 should be removed, and has revised this section accordingly. The department disagrees that sections 7.6.8.8 and 7.6.8.9 should be removed because the designation of the laboratory test sample is considered relevant and existed in ARM 37.107.405 previously. ARM 37.107.405 has since been transferred to DOR (renumbered ARM 42.39.305) and is in the process of being repealed. The language is simply being retained and moved to SOP-001.

COMMENT #73: A commenter suggested removing the term "unique" from section 7.6.9.2 of SOP-001 as Metrc tag numbers are unique numbers.

RESPONSE #73: The department agrees, and has revised SOP-001 accordingly. This will allow laboratories that use the Metrc ID as the laboratory ID to be in compliance with this section.

COMMENT #74: A commenter suggested removing the time requirement from section 7.6.9.3 of SOP-001 as it is excessive.

RESPONSE #74: The department agrees, and has revised SOP-001 accordingly.

COMMENT #75: A commenter suggested revising section 7.6.9.4.1 of SOP-001 to clarify who is responsible for the labeling requirement.

RESPONSE #75: The department agrees, and has revised SOP-001 to clarify that the task is the responsibility of the licensee.

COMMENT #76: A commenter suggested providing examples of shipping providers under section 9.5 of SOP-001.

RESPONSE #76: The department considers the existing language to be sufficiently clear and declines to make this change.

COMMENT #77: A commenter suggested adding language under section 9.7 of SOP-001 to indicate the sample report form must be in paper form and not electronic form.

RESPONSE #77: The department disagrees with the suggested revision. The section is intended to provide discretion to the testing laboratory to use paper or electronic forms for record retention.

COMMENT #78: A commenter suggested adding language to section 10.1 of SOP-001 to refer to a sampling activity more generally rather than a test batch.

RESPONSE #78: The department disagrees with the suggested revision. The intent of this section is to track and record the sampling for individual test batches and not just the sampling event.

COMMENT #79: A commenter suggested revising section 10.1.2 of SOP-001 for clarity by using the language "Name of representative from licensee submitting product(s) for testing and badge ID number" and suggested adding language to require the licensee representative signature and date.

RESPONSE #79: The department agrees, and has revised SOP-001 accordingly.

COMMENT #80: A commenter suggested adding language under section 10.1.8 to direct the reader to the percent difference equation found in SOP-001.

RESPONSE #80: The department agrees, and has revised SOP-001 accordingly.

COMMENT #81: A commenter suggested standardizing language in section 10.1.16 of SOP-001 to include the badge ID number instead of license ID number.

RESPONSE #81: The department agrees, and has revised this section of SOP-001 accordingly.

COMMENT #82: A commenter requested the department not adopt the proposed rules and SOP-001 until a cost analysis can be performed and additional feedback is sought from stakeholders. The commenter suggests proposed rules could be implemented in the summer of 2022.

RESPONSE #82: The department disagrees. The statutory provisions of HB 701 relating to marijuana sampling and testing laboratories take full effect on January 1, 2022. These provisions require the department to have rules in place governing testing laboratory endorsement requirements, sampling protocols, and parameters under which the department may suspend the license of a testing laboratory. The department has followed the requirements of the Montana Administrative Procedure Act, conducted a public hearing, and received extensive written comment on the rules. In response to these comments, the department has made significant modifications to the proposed rules. Delaying this rulemaking until the summer of 2022 would leave testing laboratories largely unregulated and would contravene the rulemaking requirements of HB 701.

COMMENT #83: A commenter suggested removal of language under section 7.1.4 of SOP-001 requiring testing laboratories to weigh test batches. The commenter indicated the language puts laboratories in the position of regulating licensees and will substantially increase sampling time. The commenter suggests program inspectors be responsible for this task.

RESPONSE #83: The department disagrees. The use of program inspectors, rather than testing laboratories, would only allow for random weight confirmations of test batches rather than weight confirmations on every occasion. Without this requirement, licensees could add extra product in a test batch to avoid testing costs. The placement of extra product in a test batch would also decrease the representativeness of the laboratory test sample and decrease the validity of the test results. The associated time requirements are necessary to ensure a quality representative sample and quality results.

COMMENT #84: A commenter suggested collecting 0.25% of the test batch and homogenizing 100% of the laboratory test sample to reduce product waste and the subsequent monetary loss to providers.

RESPONSE #84: The department disagrees. To obtain a truly representative laboratory test sample, adequate sample mass/volume must be collected. This may mean that not all the laboratory test sample collected will be used in compliance

testing. This is typical of many laboratory industries. Extra sample is also necessary for potential laboratory reruns and the necessary quality control samples required by the rule. The state of Montana has used the standard of 0.5% for many years as do many other states with marijuana programs. Additionally, the homogenization of 100% of the laboratory test sample would render filth and foreign matter screening meaningless as the seeds, stems, or other foreign material would be destroyed. Some amount of the sample must remain intact to complete this analysis.

COMMENT #85: A commenter suggested it is very difficult to manufacture edibles that are exactly 10mg and proposes that a variance such as 9 to 11mg be applicable to these products.

RESPONSE #85: This comment is outside the scope of this rulemaking on testing laboratory and sampling protocol requirements.

7. The department intends the following rules to be effective on the dates listed below:

ARM 37.107.316(6)(b), 37.107.316(6)(c), and 37.107.316(7), are effective March 14, 2022. The requirements under the existing rule for testing of culturable mold and E. coli remain in effect until this date.

8. All other referenced rules are effective the day after the date of publication.

/s/ Robert Lishman  
Robert Lishman  
Rule Reviewer

/s/ Adam Meier  
Adam Meier, Director  
Public Health and Human Services

Certified to the Secretary of State January 4, 2022.

BEFORE THE DEPARTMENT OF REVENUE  
OF THE STATE OF MONTANA

In the matter of the adoption of New	)	CORRECTED NOTICE OF
Rules I through XV, and the	)	ADOPTION AND AMENDMENT
amendment of ARM 42.39.102	)	
pertaining to the implementation of	)	
the Montana Marijuana Regulation	)	
and Taxation Act	)	

TO: All Concerned Persons

1. On October 22, 2021, the Department of Revenue (department) published MAR Notice No. 42-1033 pertaining to the public hearing on the proposed adoption and amendment of the above-stated rules at page 1369 of the 2021 Montana Administrative Register, Issue Number 20. On December 23, 2021, the department published its notice of adoption and amendment for MAR Notice No. 42-1033 at page 1937 of the 2021 Montana Administrative Register, Issue Number 24. The effective date of the department's adoptions and amendments is January 1, 2022.

2. The department has discovered (1) an inadvertent error in the numbering assigned to New Rule I upon adoption and (2) a typographical error in an implementing citation reference. As to (1), the rule number prospectively assigned to New Rule I - ARM 42.39.109 - was previously assigned to New Rule I in MAR Notice No. 42-1032, which was adopted at page 1333 of the 2021 Montana Administrative Register, Issue Number 19. As to (2), the citation in New Rules X through XV to 16-1-101, MCA, is intended to be 16-12-101, MCA.

3. To correct the unintended numbering duplication, New Rule I of this rulemaking has been assigned ARM 42.39.104. The department has also corrected the typographical error for the statutory citation.

4. The replacement pages for this corrected notice were submitted to the Secretary of State on December 31, 2021.

/s/ Todd Olson  
Todd Olson  
Rule Reviewer

/s/ David R. Stewart  
David R. Stewart  
Authorized Signor  
for the Department of Revenue

Certified to the Secretary of State January 4, 2022.

BEFORE THE DEPARTMENT OF REVENUE  
OF THE STATE OF MONTANA

In the matter of the adoption of New	)	CORRECTED NOTICE OF
Rules I through XIII pertaining to the	)	ADOPTION
implementation of compliance and	)	
enforcement requirements of the	)	
Montana Marijuana Regulation and	)	
Taxation Act and local-option	)	
marijuana excise taxation	)	

TO: All Concerned Persons

1. On November 5, 2021, the Department of Revenue (department) published MAR Notice No. 42-1040 pertaining to the public hearing on the proposed adoption of the above-stated rules at page 1513 of the 2021 Montana Administrative Register, Issue Number 21. On December 23, 2021, the department published its notice of adoption for MAR Notice No. 42-1040 at page 1964 of the 2021 Montana Administrative Register, Issue Number 24. The effective date of the department's adoptions is January 1, 2022.

2. The department has discovered an inadvertent error in the numbering assigned to New Rule XII. The rule number prospectively assigned to New Rule XII - ARM 42.39.110 - was previously assigned to New Rule II in MAR Notice No. 42-1032, which was adopted at page 1333 of the 2021 Montana Administrative Register, Issue Number 19.

3. To correct this unintended duplication, New Rule XII of this rulemaking has been assigned ARM 42.39.105.

4. The replacement pages for this corrected notice were submitted to the Secretary of State on December 31, 2021.

/s/ Todd Olson  
Todd Olson  
Rule Reviewer

/s/ David R. Stewart  
David R. Stewart  
Authorized Signor  
for the Department of Revenue

Certified to the Secretary of State January 4, 2022.

BEFORE THE SECRETARY OF STATE  
OF THE STATE OF MONTANA

In the matter of the amendment of ) NOTICE OF AMENDMENT  
ARM 44.3.2014 pertaining to )  
maintenance of active and inactive )  
voter registration lists for elections )

TO: All Concerned Persons

1. On November 19, 2021, the Secretary of State published MAR Notice No. 44-2-251 pertaining to the public hearing on the proposed amendment of the above-stated rule at page 1667 of the 2021 Montana Administrative Register, Issue Number 22.

2. On December 10, 2021, a public hearing was held on the proposed amendment of the above-stated rule. There were no attendees at the public hearing. Written comments were received during the public comment period.

3. The Secretary of State has amended the following rule as proposed, but with the following changes from the original proposal, deleted matter interlined:

44.3.2014 MAINTENANCE OF ACTIVE AND INACTIVE VOTER  
REGISTRATION LISTS FOR ELECTIONS (1) remains as proposed.

(2) An election administrator performing the procedures outlined in 13-2-220(1)(a) ~~or (b)~~, MCA, in the month of January also satisfies the requirements of 13-13-212(4)(b), MCA.

4. The Secretary of State has thoroughly considered the comments received. A summary of the comments and SOS's responses are as follows:

COMMENT #1: A commenter said that option (b) under 13-2-220(1), MCA provides that an election administrator may mail a "nonforwardable, first-class, 'return if undeliverable -- address correction requested' notice to all registered electors of each jurisdiction to confirm their addresses and provide the 'appropriate confirmation notice.'" Although the nonforwardable notice must be followed by a forwardable notice to any elector who fails to respond within 30 days, the forwardable notice must be mailed in January of an even-numbered year to concurrently satisfy the absentee ballot list maintenance requirements of 13-13-212(4)(b), MCA. Because of the complexity of ensuring the requirements of both statutes are met within the required timeframe, the commenter believes it would be difficult if not impossible to complete.

RESPONSE #1: The Secretary of State agrees and has removed that option.

COMMENT #2: A commenter said that since the Secretary of State is upgrading the voter registration software, now would be a good time to have all voters re-register.

RESPONSE #2: The 2021 legislative enactments implemented by this proposed rule amendment (Senate Bill 170) do not require re-registration of all voters.

COMMENT #3: A commenter said the Secretary of State's Office should encourage election administrators to conduct the procedures in 13-2-220(1)(a) or (b) and (c), MCA, in addition to reviewing all prior 12 months' death notification lists to determine if any changes were inadvertently missed.

RESPONSE #3: Section 13-2-220, MCA requires that election administrators follow "at least one" annually. Election administrators may choose to do more than one option.

COMMENT #4: A commenter said the Secretary of State's Office should conduct random, unannounced verification of election officials' maintenance of active and inactive voter registration lists.

RESPONSE #4: The Secretary of State's Office is currently able to verify list maintenance activity; therefore, inclusion in administrative rule is unnecessary.

COMMENT #5: A commenter said the Secretary of State's Office should require voter records to reflect two eligibility dates – the initial registration date and, if applicable, the date of re-registration for inactive voters, voter address change, or other registration updates.

RESPONSE #5: Changes to voter records are captured in the voter registration system. Voter registration system functionality and software features are not established in administrative rule.

COMMENT #6: A commenter said the Secretary of State's Office should require county election offices to perform an address verification of the entire voter registration database 30 days prior to any mail-in election.

RESPONSE #6: The 2021 legislative enactments implemented by this proposed rule amendment (Senate Bill 170) do not require an additional address verification 30 days prior to any mail-in election.

COMMENT #7: A commenter said the Secretary of State's Office should require elector's information be concealed beneath the flap of the signature envelope for all absentee and mail-in elections.

RESPONSE #7: The 2021 legislative enactments implemented by this proposed rule amendment (Senate Bill 170) do not address this issue.



/s/ AUSTIN JAMES

Austin James  
Rule Reviewer

/s/ ANGELA NUNN

Angela Nunn  
Chief Deputy Secretary of State

Dated this 4th day of January, 2022.

## **NOTICE OF FUNCTION OF ADMINISTRATIVE RULE REVIEW COMMITTEE**

### **Interim Committees and the Environmental Quality Council**

Administrative rule review is a function of interim committees and the Environmental Quality Council (EQC). These interim committees and the EQC have administrative rule review, program evaluation, and monitoring functions for the following executive branch agencies and the entities attached to agencies for administrative purposes.

#### **Economic Affairs Interim Committee:**

- Department of Agriculture;
- Department of Commerce;
- Department of Labor and Industry;
- Department of Livestock;
- Office of the State Auditor and Insurance Commissioner; and
- Office of Economic Development.

#### **Education and Local Government Interim Committee:**

- State Board of Education;
- Board of Public Education;
- Board of Regents of Higher Education; and
- Office of Public Instruction.

#### **Children, Families, Health, and Human Services Interim Committee:**

- Department of Public Health and Human Services.

#### **Law and Justice Interim Committee:**

- Department of Corrections; and
- Department of Justice.

#### **Energy and Telecommunications Interim Committee:**

- Department of Public Service Regulation.

**Revenue and Transportation Interim Committee:**

- Department of Revenue; and
- Department of Transportation.

**State Administration and Veterans' Affairs Interim Committee:**

- Department of Administration;
- Department of Military Affairs; and
- Office of the Secretary of State.

**Environmental Quality Council:**

- Department of Environmental Quality;
- Department of Fish, Wildlife and Parks; and
- Department of Natural Resources and Conservation.

**Water Policy Interim Committee (where the primary concern is the quality or quantity of water):**

- Department of Environmental Quality;
- Department of Fish, Wildlife and Parks; and
- Department of Natural Resources and Conservation.

These interim committees and the EQC have the authority to make recommendations to an agency regarding the adoption, amendment, or repeal of a rule or to request that the agency prepare a statement of the estimated economic impact of a proposal. They also may poll the members of the Legislature to determine if a proposed rule is consistent with the intent of the Legislature or, during a legislative session, introduce a bill repealing a rule, or directing an agency to adopt or amend a rule, or a Joint Resolution recommending that an agency adopt, amend, or repeal a rule.

The interim committees and the EQC welcome comments and invite members of the public to appear before them or to send written statements in order to bring to their attention any difficulties with the existing or proposed rules. The mailing address is P.O. Box 201706, Helena, MT 59620-1706.

## HOW TO USE THE ADMINISTRATIVE RULES OF MONTANA AND THE MONTANA ADMINISTRATIVE REGISTER

### Definitions:

**Administrative Rules of Montana (ARM)** is a looseleaf compilation by department of all rules of state departments and attached boards presently in effect, except rules adopted up to three months previously.

**Montana Administrative Register (MAR or Register)** is an online publication, issued twice-monthly, containing notices of rules proposed by agencies, notices of rules adopted by agencies, and interpretations of statutes and rules by the Attorney General (Attorney General's Opinions) and agencies (Declaratory Rulings) issued since publication of the preceding Register.

### Use of the Administrative Rules of Montana (ARM):

Known  
Subject

1. Consult ARM Topical Index.  
Update the rule by checking recent rulemaking and the table of contents in the last Montana Administrative Register issued.

Statute

2. Go to cross reference table at end of each number and title which lists MCA section numbers and department corresponding ARM rule numbers.

## RECENT RULEMAKING BY AGENCY

The Administrative Rules of Montana (ARM) is a compilation of existing permanent rules of those executive agencies that have been designated by the Montana Administrative Procedure Act for inclusion in the ARM. The ARM is updated through September 30, 2021. This table includes notices in which those rules adopted during the period July 23, 2021, through December 23, 2021, occurred and any proposed rule action that was pending during the past 6-month period. (A notice of adoption must be published within six months of the published notice of the proposed rule.) This table does not include the contents of this issue of the Montana Administrative Register (MAR or Register).

To be current on proposed and adopted rulemaking, it is necessary to check the ARM updated through September 30, 2021, this table, and the table of contents of this issue of the Register.

This table indicates the department name, title number, notice numbers in ascending order, the subject matter of the notice, and the page number(s) at which the notice is published in the 2021 Montana Administrative Registers.

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